VA Human Research Protection Accreditation Program Accreditation Standards

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NCQA
Measuring the Quality of America's Health Care

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Definitions

ADVERSE EVENT (AE) – Any untoward event associated with a research study. The event does not necessarily have a causal relationship with treatment or study intervention. An AE can be any unfavorable and unintended sign, symptom or disease.

AFFILIATE'S HUMAN RESEARCH PROTECTION PROGRAM – The HRPP of a VAMC's academic affiliate. See HRPP.

ASSURANCE – See FEDERALWIDE ASSURANCE, MULTIPLE PROJECT ASSURANCE, AND VA MULTIPLE PROJECT ASSURANCE.

CERTIFICATE OF CONFIDENTIALITY – Where data are being collected from subjects about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences), researchers can obtain an advance grant of confidentiality from the Public Health Service that will provide protection against involuntary disclosure of the research subjects identity and the subject's participation in the study, even against a subpoena for research data.

CONTINUING REVIEW – Periodic review by the IRB of active research for the purpose of re-approving, requiring modifications, disapproving, terminating or suspending the study. CONTINUING REVIEW must occur at least annually, as determined by the IRB. See also ONGOING MONITORING.

DOMAIN – A logical grouping of standards. Within the standards, there is a hierarchy of organization. The DOMAIN is the highest level of the hierarchy, and provides organization. Within each DOMAIN, standards are grouped into STANDARDS, REQUIREMENTS, ELEMENTS and FACTORS. The standards are organized into six DOMAINS: Institutional Responsibilities; IRB Structure and Operations; Consideration of Risks and Benefits; Recruitment and Subject Selection; Privacy and Confidentiality; Informed Consent.

ELEMENT – A component of a REQUIREMENT. REQUIREMENTS are made up of multiple ELEMENTS, each of which can be separately assessed and which provide additional detail about the performance expectation.

FACTOR – One part, or component, of an ELEMENT. ELEMENTS may be made up of one or more FACTORS.

FDA FORM 3454 – The financial disclosure form required by the FDA to reveal/identify any potential financial conflict of interest that an investigator(s), sub-investigator(s) or their spouse and children may have that is applicable to the submission of marketing applications for human drug, biological product, or device for each covered study.

FEDERALWIDE ASSURANCE (FWA) – An agreement or contract between the institution and OHRP, on behalf of the Secretary, DHHS, stipulating the method(s) by which the organization will protect the welfare of research subjects in accordance with the regulations. The Assurance, approval of which is a condition of receipt of DHHS support for research involving human subjects, spells out the organization's responsibilities for meeting the requirements of 45 CFR 46. The FWA replaces all other

previous forms of assurance (i.e., MPA, SPA, VA MPA, etc.). All VA facilities conducting human research will be required to maintain an FWA.

FOOD AND DRUG ADMINISTRATION (FDA) – The Federal agency responsible for the regulation of food, drugs and cosmetics, including the human subject research performed for FDA-regulated articles.

HUMAN RESEARCH PROTECTION PROGRAM (HRPP) – The systematic and comprehensive approach by an organization to ensure human subject protection in all research. The implementation of any part of the program may be delegated to specific committees, individuals or entities (i.e., academic affiliate or another VAMC) by the organization.

HUMAN SUBJECT – A living individual about whom a research investigator (whether professional or student conducting research) obtains data through intervention or interaction with the individual or identifiable information.

HUMAN SUBJECT SUBCOMMITTEE (of the R&D Committee) – The VAMC's IRB is constituted as a subcommittee to the R&D Committee.

INSTITUTION – Refers to an individual VAMC/HCS. The institution retains ultimate responsibility for human subject protection in research conducted at their facility and/or by their staff.

INSTITUTIONAL REVIEW BOARD (IRB) – An independent committee comprised of scientific and non-scientific members established according to the requirements outlined in Title 38, part 16 (same as Title 45, part 46 and Title 21, part 56) of the U. S. Code of Federal Regulations. The IRB may also be referred to as the HUMAN STUDIES SUBCOMMITTEE of the R&D Committee. Other committees with the same or similar functions are also considered to be IRBs.

INVESTIGATIONAL DEVICE EXEMPTION (IDE) – The process by which the FDA permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device.

INVESTIGATIONAL NEW DRUG APPLICATION (IND) – The process by which new drugs or biologics, including the new use of an approved drug, are registered with the FDA for administration to human subjects. An IND number is assigned by the FDA to the drug or biologic for use in tracking.

INVESTIGATOR (Principal investigator) – An individual who conducts an investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

INVESTIGATOR/SPONSOR – A term defined in the FDA regulations as an individual with responsibility for initiating and conducting a research study.

IRB DOCUMENTATION – Any written evidence of the IRB's consideration, evaluation, and/or assessment of proposed or active research.

LEGALLY AUTHORIZED REPRESENTATIVE – An individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in research.

MEDWATCH - The FDA Medical Products Reporting Program, is an initiative designed both to educate all health professionals about the critical importance of being aware of, monitoring for, and reporting adverse events and problems to FDA and/or the manufacturer and to ensure that new safety information is rapidly communicated to the medical community, thereby improving patient care. The purpose of the MedWatch program is to enhance the effectiveness of postmarketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products.

MEMORANDUM OF UNDERSTANDING (MOU) – A written agreement outlining the details of the relationship between organizations, including the responsibilities of each. Such an agreement is used by the VAMC to delineate the terms and conditions under which it may utilize another entity's IRB.

MINIMAL RISK – The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

MULTIPLE PROJECT ASSURANCE (MPA) – An agreement or contract between the institution and OPRR, on behalf of the Secretary, DHHS, stipulating the method(s) by which the organization will protect the welfare of research subjects in accordance with the regulations. The Assurance, approval of which is a condition of receipt of DHHS support for research involving human subjects, spells out the organization's responsibilities for meeting the requirements of 45 CFR 46. MPAs will be replaced by FWAs.

ONGOING MONITORING – Review by the IRB of such information as adverse event reports, protocol amendments, reports of protocol deviations, and other information about ongoing research studies, during the period for which the protocol is approved.

POLICY – A written principle or rule to guide decision-making.

PRACTICE – An activity that is actually routinely performed, regardless of whether it is required in POLICY or specified in PROCEDURE.

PROCEDURE – See Standard Operating Procedure (SOP).

PROTOCOL – A plan that includes, at minimum, the objectives, rationale, design, methods and other conditions for the conduct of a research study.

PROTOCOL FILE – The documents maintained by the IRB administration containing the protocol, investigator's brochure, IRB/investigator communications and all other supporting materials.

QUALITY IMPROVEMENT (QI) – The effort to assess and improve the level of performance of a program or institution. QI includes quality assessment and implementation of corrective actions to address any deficiencies identified.

R&D COMMITTEE – The Research and Development Committee of the VAMC. This committee has numerous responsibilities for Human Research Protection.

REQUIREMENT – A statement of performance expectations for the Institution's Human Research Protection Program or its IRB. Requirements are composed of ELEMENTS.

RESEARCH - A systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

SAFETY REPORTS (IND/IDE) – Written reports from sponsors notifying the FDA and all participating investigators of any adverse experience associated with the use of a drug that is both serious and unexpected.

SERIOUS ADVERSE EVENT (SAE) – Any event that results in death, a life threatening situation, hospitalization or prolonged hospitalization, persistent or significant disability/incapacity or a congenital anomaly/birth defect. SAEs require reporting to the sponsor and the IRB.

SPONSOR – Any person or entity who takes responsibility for and initiates a clinical study. The sponsor may be an individual, pharmaceutical company, device manufacturer, governmental agency, academic institution, private organization, or other organization.

STANDARD -- A broad description of performance expectation. In this document, standards serve as topical headings for REQUIREMENTS.

STANDARD OPERATING PROCEDURE (SOP) – A written set of methods or steps to be followed for the uniform performance of a function or activity.

UNEXPECTED ADVERSE EVENT – Any adverse event that has not previously been observed (e. g., included in the investigator brochure).

VA MULTIPLE PROJECT ASSURANCE CONTRACTS - VA MPA Contracts are between the individual VAMC or HCS and VHA Central Office, Office of Research and Development. The VA will convert all "Letters of Assurance" VA MPA Contracts to FWA during calendar year 2001.

VULNERABLE SUBJECTS – Individuals whose willingness to volunteer in a research study may be unduly influenced or coerced and individuals with limited autonomy. These individuals may include, but are not limited to, children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged persons.

Topic Area **Institutional Responsibilities (INR)**

Rationale *Each VA Medical Center (VAMC) engaged in research involving human subjects is responsible for ensuring the rights, safety and well-being of those recruited to participate in research activities. As a research institution, it is also responsible for assuring that investigators and their staffs understand and comply with standards for the ethical conduct of research. These broad responsibilities can be met through three institutional actions: developing a systematic and comprehensive approach, a Human Research Protections Program (HRPP), to monitor, evaluate and improve the protection of human research subjects; establishing and/or designating an Institutional Review Board (IRB) to review research following Federal and institutional requirements; and educating staff involved in research about their ethical responsibility to protect research subjects. This standard outlines the responsibilities of institutions that conduct human subjects research.*

INRI	**The institution has a systematic and comprehensive program, a Human Research Protection Program (HRPP), with dedicated resources to ensure the rights, safety and well being of human research subjects in relation to their participation in research activities.**

Requirement INR1	**The institution has a written description of (or plan for) its HRPP appropriate for the research involving human subjects conducted at the institution.**			
Element INR1A	The HRPP description includes the following: 1. Statement of principles concerning protection of human research subjects. 2. Identification of the institutional officer accountable for the HRPP. 3. The organizational structure, process, roles and responsibilities for making policy to protect human research subjects. 4. Roles and responsibilities of the R&D Committee in protecting human subjects. 5. One or more of the following arrangements for an IRB: the institution has a Human Subjects Subcommittee to R&D Committee and registers it with OHRP; the institution has a written arrangement with a regional VA IRB or another VA IRB that is registered with OHRP; the institution has a written arrangement with an affiliated medical or dental school or university for the use of its registered IRB.			
Weight (1-5)	3			
Scoring Guidelines	100%	75%	50%	0%
	HRPP description includes five factors.	NA	NA	HRPP description includes less than five factors.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(1), 38CFR16.103(c), M-3, Part I, 2.02b, M-3, Part I, 3.01b, M-3, Part I, 9.07, 45CFR46.103(b)(1), 45CFR46.103(c), IRB Guidebook (1), MPA			
Data Source	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: MPA, institutional organizational charts, job descriptions, policies and procedures (IRB and institution), budget/time allocation, formal IRB agreement, R&D Committee charter.			

Element INR1B	The institution's Research and Development (R&D) Committee conforms to VA policy regarding Human Subjects Research. Responsibilities include the following: 1. The R&D Committee is responsible for the scientific quality and appropriateness of all research involving human subjects. 2. The R&D Committee re-evaluates at least annually, the scientific quality of all research studies involving human subjects to assure protection of human subjects. 3. The R&D Committee membership, supplemented as needed by advisors or consultants, possesses the expertise required to perform the scientific review. 4. The R&D Committee cannot alter an adverse report or recommendation, e.g., disapproval for ethical or legal reasons made by the Subcommittee on Human Studies.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	R&D Committee meets all four factors.	NA	NA	R&D Committee meets less than four factors.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	M-3, Part I, 2.02b(1), M-3, Part I, 2.02b(2), M-3, Part I, 3.01a(4), M-3, Part I, 3.01b(1), M-3, Part I, b3(a-b), M-3, Part I, 3.01d(5)(e)			
Data Source	Documented process, reports			
Notes	Examples of documents that may demonstrate compliance with this element include: R&D Committee charter, R&D or institutional policies and procedures, R&D membership list, R&D minutes.			
Element INR1C	A designated committee or individual (e.g., R&D Committee or ACOS for R&D) ensures that the HRPP is operational. The following specific responsibilities are outlined in job descriptions, committee charters or other documents: 1. Implementation of the institution's HRPP policy. 2. Review and evaluation of the reports and results of compliance assessment and quality improvement activities. 3. Implementation of needed improvements and follow-up on actions, as appropriate. 4. Monitoring changes in VA and other Federal regulations and policies that relate to human research protections.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	All four responsibilities are identified.	Three responsibilities are identified.	Two responsibilities are identified.	Less than two responsibilities are identified.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	38CFR16.103(c), IRB Guidebook I			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: R&D or institutional policies and procedures, job descriptions, committee charters.			

Element INR1D	The institution maintains and supports a current and approved Federalwide Assurance (FWA) and/or an assurance in accordance with current VA regulations that includes its principles and guidelines for protecting research subjects. The institution demonstrates its maintenance and support of its assurance by the following: 1. The institution is operating under a current approved assurance. 2. The institution identifies the responsible official for the assurance (Note: In VA facilities, the Medical Center Director/CEO is the responsible official). 3. If the assurance is an FWA, it is approved by the VA Office of Research Compliance and Assurance (ORCA).			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	The institution maintains and supports an assurance as required.	NA	NA	The institution does not maintain an assurance.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(a), M-3, Part I, 9.03c, 45CFR46.103(a), FWA, ORCA Directive 2c-201-5, VA MPA			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: FWA, VA Letter of Assurance with any of the following - MPA with OHRP, VA MPA Contract, IIA with MPA/ FWA institution.			
Element INR1E	For each commitment of the institution's assurance, the institution has corresponding documented processes for implementation. The documented processes: 1. Address commitments made in the assurance. 2. Do not contradict commitments made in the assurance.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Each commitment has a corresponding documented process.	75% of the commitments have a documented process.	50% of the commitments have a documented process.	Less than 50% of the commitments have a documented process.
Scope of Review	NCQA reviews this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	IRB Guidebook I, MPA			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: institutional, IRB and R&D Committee policies and procedures.			

Requirement INR2	The institution provides sufficient resources for the HRPP, R&D Committee and its IRB(s)			
Element INR2A	The institution engages in a systematic budgeting process for the HRPP including the R&D Committee and if applicable, its Human Subjects Subcommittee (IRB) at least annually. Budgeting includes consideration of the following factors: 1. Analysis of the volume of research to be reviewed. 2. Feedback from IRB members and staff.			
Weight (1-5)	3			
Scoring Guidelines	100%	75%	50%	0%
	Budgeting includes consideration of two factors.	NA	Budgeting includes consideration of one factor.	Budgeting includes consideration of less than one factor.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	M-3, Part I, 3.01b(1), M-3, Part I, 3.02g(1), IRB Guidebook, MPA			
Data Sources	Reports			
Notes	Examples of documents that may demonstrate compliance with this element include: budget records, institutional policy regarding budget, IRB forms.			
Element INR2B	During the budgeting process, resources reviewed include but are not limited to: 1. Personnel. 2. Materials and supplies. 3. Space. 4. Capital Equipment. 5. Training and education.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Budget review includes all five factors.	Budget review includes three factors.	Budget review includes two factors.	Budget review includes less than two factors.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	M-3, Part I, 3.01(b)(1), M-3, Part I, 3.02(g)(1), IRB Guidebook, MPA			
Data Sources	Reports			
Notes	Examples of documents that may demonstrate compliance with this element include: budget records, institutional policy regarding budget, budget analysis forms, reports.			

Element INR2C	The institution must be able to ascertain the following for each active research proposal: 1. Date originally approved and if applicable, date of most recent approval. 2. Date of expiration of approval.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	The institution tracks two factors.	NA	The institution tracks one factor.	The institution tracks less than two factors.
Scope of Review	NCQA evaluates this element once for the institution and once for each external IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.115(a), 45CFR46.115(a), 21CFR56.115(a), FDA Information Sheets – Self Evaluation Checklist for IRB's, IRB Guidebook I, III			
Data Sources	Reports			
Notes	Examples of documents or methods that may demonstrate compliance with this element include: database reports, IRB files, log sheets, reports, live system queries.			

Requirement INR3	**The institution provides proper oversight to its IRB(s).**				
Element INR3A	If the institution uses the IRB(s) of a VA regional system, affiliated university or another VA facility, there is a legal document, e.g. Memorandum of Understanding (MOU), contract or letter of agreement (Formal IRB Agreement). This document, includes, at a minimum: 1. Specific requirements for the membership and operation of the IRB to review VA research in compliance with VA regulations. 2. The respective responsibilities of the institution and the designated IRB for human subject protection. 3. The scope of activities delegated to the IRB. 4. The method, frequency and nature of reporting to the R&D Committee. 5. The process by which the institution evaluates the IRB's performance. 6. The remedies, including revocation of the Formal IRB Agreement, available to the institution if the designated IRB does not fulfill its obligations.				
Weight	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	Formal IRB Agreement includes all six factors.	Formal IRB Agreement includes five factors.	Formal IRB Agreement includes four factors.	There is no Formal IRB Agreement or it includes less than four factors.	The institution has its own IRB.
Scope of Review	NCQA evaluates this element for <u>each</u> external IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-3, Part I, 3.01e, M-3, Part I, 9.07a, M-3, Part I, 9.16				
Data Sources	Documented Process				
Notes	The only documents that may be used to demonstrate compliance with this element are Formal IRB Agreements that may be contained within other broader inter-institutional agreements or legal documents.				

Element INR3B	If the institution has used the IRB(s) of a VA regional system, affiliated university or another facility for one year or longer, the institution conducts oversight of the designated IRB(s) including the following: 1. Regularly evaluating reports as required in the Formal IRB Agreement. 2. Annually reviewing designated IRB's charter, policies and procedures. 3. Annually evaluating whether the designated IRB is in compliance with current VA, Federal and other regulations and guidance.				
Weight (1-5)	3				
Scoring Guidelines	100%	75%	50%	0%	NA
	Oversight includes all three factors.	Oversight includes two factors.	Oversight includes one factor.	Oversight is not performed, or does not include any factor.	Institution has used the external IRB for less than 1 year.
Scope of Review	NCQA evaluates this element for <u>each</u> external IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-3, Part I, 3.01e(1)(c)				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: R&D Committee minutes, IRB performance reports, correspondence with IRB regarding performance findings.				

Element INR3C	If the institution has used the IRB(s) of a VA regional system, affiliated university or another VA facility for less than one year, the institution conducts oversight of the designated IRB(s) including the following: 1. Prior to designation, evaluates designated IRB's capacity to perform the designated activities. 2. Regularly evaluates reports as required in the Formal IRB Agreement.				
Weight (1-5)	3				
Scoring Guidelines	100%	75%	50%	0%	NA
	Oversight includes both factors.	NA	Oversight includes one factor.	Oversight is not performed or includes less then one factor.	The institution has used the IRB for 1 year or longer.
Scope of Review	NCQA evaluates this element for <u>each</u> external IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-3, Part I, 3.01e(1)(c)				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: R&D Committee minutes, IRB performance reports, correspondence with IRB regarding performance findings.				

Element INR3D	Whether the IRB is internal or external to the institution, the institution at least annually reviews and documents consideration of the following: 1. The IRB(s) and the membership of the IRB(s) are appropriate given the research being reviewed. 2. The IRB(s) includes representatives with an interest in or experience with vulnerable populations involved in research, either as members or ad hoc consultants.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	
	The institution annually reviews two factors.	NA	The institution annually reviews one factor.	The institution does not annually review either factor.	
Scope of Review	NCQA evaluates this element for <u>each</u> IRB (internal or external).				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.107(a), M-3, Part I, 3.01(b)(1), 45CFR46.107(a), 21CFR56.107(a), VA MPA				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: R&D Committee minutes, IRB performance reports, correspondence with IRB regarding performance findings.				
Element INR3E	The R&D Committee assesses the qualifications and experience of the IRB Chair prior to appointment.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	The R&D Committee assesses the qualifications and experience of the chair.	NA	NA	The R&D Committee does not assess the qualifications and experience of the chair.	No change in IRB Chair in the last year.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support					
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: R&D Committee minutes, R&D Committee communications				

Element INR3F	The institution evaluates the performance of the IRB(s). Evaluation includes the following areas: 1. Content and accuracy of informed consent forms. 2. IRB analysis of risks and benefits including designation of minimal risk. 3. Special considerations and protections for vulnerable or potentially vulnerable populations. 4. Privacy and confidentiality protections. 5. Continuing review of approved research. 6. Ongoing review of previously approved research (i.e. amendments, adverse events). 7. Use of expedited review or other procedures requiring review of less than the full IRB. 8. Granting exemption from Federal requirements for IRB review. 9. Granting waivers for documentation of informed consent. 10. Granting waivers of any elements of informed consent.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	Evaluation includes all ten factors.	Evaluation includes eight factors.	Evaluation includes six factors.	Evaluation is not performed or includes less than six factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	M-3, Part I, 3.01e(1)(c)			
Data Sources	Reports			
Notes	Examples of documents that may demonstrate compliance with this element include: R&D Committee minutes, IRB performance reports, correspondence with IRB regarding performance findings.			

Requirement INR4	**The institution has policies and procedures to identify and manage institutional, IRB member and investigator conflicts of interest with research conducted at the institution.**			
Element INR4A	The institution has policies and procedures for the identification and management of conflict of interest of IRB members.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	The institution has policies and procedures addressing the element.	NA	NA	The institution does not have policies and procedures addressing the element.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.107(e), M-3, Part I, 9.08(e), 45CFR46.107(e), 21CFR56.107(e)			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB, institutional, or R&D policies and procedures, IRB and R&D Committee minutes.			
Element INR4B	The institution has policies and procedures for the identification and management of conflicts of interest of the following parties: 1. Institution, including the R&D Committee. 2. Investigators.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address both parties.	NA	Policies and procedures address one party.	Policies and procedures do not address either party.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	21CFR312.64(d)			
Data Sources	Documented Process			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB, R&D, or institutional policies and procedures.			

Requirement INR5	**The institution has a process that enables research subjects and others to ask questions or to voice concerns or complaints.**			
Element INR5A	The institution has policies and procedures for responding to complaints and allegations of noncompliance with institutional policies. The system includes the following factors: 1. Ensuring a response to each question, concern or complaint. 2. Investigating complaints and allegations. 3. Taking remedial action for, and consequences of findings of, noncompliance with HRPP and IRB policies. 4. Identifying individuals who have responsibility for responding to questions, concerns or complaints regarding an individual's rights as a research subject.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all four factors.	Policies and procedures address three factors.	Policies and procedures address two factors.	Policies and procedures address less than two factors.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(c), 38CFR16.116(a)(7), M-3, Part I, Chapter 3, Appendix 9C, 45CFR46.103(c), 45CFR46.116(a)(7), 21CFR50.25(a)(7), ICH Guidelines 4.8.10(q), IRB Guidebook III			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB, R&D, and institutional policies and procedures.			
Element INR5B	The institution actively seeks feedback about its research program through surveys, focus groups, interviews or other methods. The institution seeks feedback from any of the following: 1. Current research subjects. 2. Former research subjects. 3. Potential research subjects (e.g., patients, whether or not eligible for a specific protocol). 4. Individuals who have declined to participate in research. 5. Research subject advocates.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Feedback solicited from two or more identified groups.	Feedback solicited from one identified group.	NA	No feedback sought.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	Institute of Medicine, "*Preserving the Public Trust. Accreditation and Human Research Participant Protection Programs."*			
Data Sources	Reports			
Notes	Examples of documents that may demonstrate compliance with this element include: analyses or reports of findings.			

Requirement INR6	The institution ensures that the use of investigational products in research with human subjects is consistent with VA and Federal regulations.				
Element INR6A	The institution's Pharmacy Service has policies and procedures for handling investigational drugs that address the following factors: 1. Receipt. 2. Storage. 3. Security. 4. Dispensing. 5. Disposition of unused stock.				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Policies and procedures address all five factors.	Policies and procedures address four factors.	Policies and procedures address three factors.	Policies and procedures address less than three factors.	The institution does not conduct investigational drug research.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-2, Part VII, 6.03 a and g, 21CFR312.61, 21CFR312.62, VA Form 10-9012				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: institutional or pharmacy service policies and procedures.				
Element INR6B	The Pharmacy Service maintains an investigational drug log which includes the following: 1. Name of drug. 2. Manufacturer or other source. 3. Date of receipt of the drug. 4. Quantity received. 5. Expiration date. 6. Control number. 7. Date protocol approved. 8. Name of authorized practitioner signing the prescription.				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Investigational drug logs include all eight factors.	Investigational drug logs include seven factors.	Investigational drug logs include six factors.	Investigational drug logs include less than six factors.	The institution does not conduct investigational drug research.
Scope of Review	NCQA selects three drug studies and evaluates the investigational drug log for each.				
Accreditation	0% ⇒Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-2, Part VII, 6.03g(1-8), 21CFR312.61, 21CFR312.62				
Data Sources	Reports				
Notes	Examples of documents and methods that may demonstrate compliance with this element include: investigational drug logs (paper or electronic).				

Element INR6C	For each research subject, the Pharmacy Service maintains the following information in the investigational drug log: 1. Name of the patient receiving the prescription. 2. Serial number of the prescription. 3. Quantity dispensed. 4. Balance remaining after the transaction.				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Investigational drug logs include all four factors for each subject.	NA	Investigational drug logs include three factors for each subject.	Investigational drug logs include less than three factors for each subject.	The institution does not conduct investigational drug research
Scope of Review	NCQA selects three drug studies and evaluates the investigational drug log for each.				
Accreditation	0% ⇒Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-2 Part VII 6.03g(9-12)				
Data Sources	Reports				
Notes	Examples of documents and methods that may demonstrate compliance with this element include: investigational drug logs (paper or electronic).				

Element INR6D	The investigational drug log includes a final entry when the use of the investigational drug is discontinued. This entry documents the following: 1. Date of termination of use of drug. 2. Quantity remaining. 3. Action taken to dispose of the balance on hand.				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Final entries in investigational drug logs document all three factors.	NA	NA	Final entries in investigational drug logs document less than three factors.	The institution does not conduct investigational drug research.
Scope of Review	NCQA selects from three completed drug studies and evaluates the investigational drug log for each.				
Accreditation	0% ⇒Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-2, Part VII, 6.03g(14)				
Data Sources	Reports				
Notes	Examples of documents and methods that may demonstrate compliance with this element include: investigational drug logs (paper or electronic).				

Element INR6E	The Pharmacy Service ensures that investigational drugs are not dispensed without the following on file: 1. Approved protocol. 2. Signed informed consent form. 3. VA Form 10-9012 (Investigational Drug Information Record).				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Files contain all three factors.	NA	NA	Files contain less than three factors.	The institution does not conduct investigational drug research.
Scope of Review	NCQA selects three drug studies and evaluates the files for each, including files for up to five subjects dispensed investigational drugs in each study.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-2, Part VII, 6.02c				
Data Sources	Records or files				
Notes	For each drug study reviewed, surveyors will review five entries and ask to see the signed consent form for each subject dispensed investigational drugs.				

Element INR6F	The Pharmacy Service evaluates its compliance with policies and procedures regarding the use of investigational drugs. Evaluations address the following factors: 1. Receipt. 2. Storage. 3. Security. 4. Dispensing. 5. Disposition.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	Evaluation addresses all five factors.	Evaluation addresses four factors.	Evaluation addresses three factors.	Evaluation addresses less than three factors.	The institution does not conduct investigational drug research.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	M-2, Part VII, 6.02, 21CFR312.61, 21CFR312.62				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality assurance reports, consultant reports, minutes, documentation, review of performance.				

Element INR6G	Results of Pharmacy Service evaluations are reported to the R&D Committee (or other institutional official with responsibility for oversight of the research pharmacy).				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	NA
	Evaluations are reported.	NA	NA	Evaluations are not reported.	The institution does not conduct investigational drug research.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	M-2 Part VII, 6.02				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: R&D Committee minutes, QA reports acknowledged by institutional official.				

Element INR6H	If areas of noncompliance are identified, the Pharmacy Service implemented corrective action (e.g., changes policy, procedure, communication, implements education, or other intervention) to restore compliance.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	Pharmacy Service implemented corrective action to address all identified areas of noncompliance.	Pharmacy Service implemented corrective action to address at least half of the identified areas of noncompliance.	NA	Pharmacy Service implemented corrective action on less than half of the identified areas of noncompliance.	No areas of noncompliance identified.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.103(a), MPA				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality improvement reports, R&D Committee minutes, changes to policies and procedures, and other documentation of action taken.				

Element INR6I	The institution has policies and procedures regarding the use of investigational devices that address the following factors: 1. Storage. 2. Security. 3. Dispensing.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	NA
	Policies and procedures address all three factors.	NA	Policies and procedures address two factors.	Policies and procedures address less than two factors.	The institution does not conduct investigational device research.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	21CFR812.140				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, flow charts, protocols or other mechanisms that describe a process used by the institution.				

Requirement INR7	**The institution evaluates HRPP effectiveness and conducts quality improvement activities. Evaluation and improvement include measuring, assessing, and improving compliance with institutional HRPP policies, assurances and other requirements for the protection of human subjects in research.**			
Element INR7A	The institution monitors the performance of investigators to ensure compliance with HRPP and IRB requirements. The institution evaluates the following: 1. Using only IRB-approved advertisements and subject recruitment materials. 2. Obtaining IRB approval prior to initiating changes to the protocol or consent form, except where necessary to eliminate apparent immediate hazards to subjects. 3. Reporting all unanticipated problems involving risks to human subjects. 4. Reporting all protocol deviations. 5. Adherence to HRPP policies. 6. Adherence to IRB approved protocols and conditions.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Evaluation includes all six factors.	Evaluation includes four factors.	Evaluation includes three factors.	Evaluation includes less than three factors.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(4)(iii), 38CFR16.103(b)(5)(i), M-3, Part I, 9.09(f), 45CFR46.103(b)(4)(iii), 45CFR46.103(b)(5)(i), FDA Information Sheets – Recruiting Study Subjects, FWA, IRB Guidebook IIII H, VA MPA			
Data Sources	Reports			
Notes	Examples of documents that may demonstrate compliance with this element include: minutes from IRB or R&D Committee or Quality Improvement Committee, quality assurance or improvement reports, internal or external audit or monitoring reports, investigator performance evaluations.			

Element INR7B	The institution monitors the performance of investigators in implementing informed consent requirements. The institution evaluates the following: 1. Obtaining consent prior to initiating any research related procedures. 2. Using only the IRB-approved consent form. 3. Signing and dating the consent form. 4. Documenting consent in the case history. 5. Providing a copy of the consent form to the subject or legally authorized representative.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Evaluation includes all five factors.	Evaluation includes four factors.	Evaluation includes three factors.	Evaluation includes less than three factors.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater then Accredited with Conditions			
Regulatory Support	38CFR16.109(b), 38CFR16.116, 45CFR46.109(b), 45CFR46.116, 21CFR50.27, 21CFR56.109(b), 21CFR312.62(b), FDA Information Sheets – Guide to Informed Consent, FWA, IRB Guidebook I			
Data Sources	Reports			
Notes	Examples of documents that may demonstrate compliance with this element include: minutes from IRB or R&D Committee or Quality Improvement Committee, quality assurance or improvement reports, internal or external audit or monitoring reports, investigator performance evaluations.			
Element INR7C	The institution monitors its responsiveness to questions, concerns and complaints: 1. Timeliness of responses to questions and complaints. 2. Satisfaction with responses.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	The institution monitors both factors.	NA	The institution monitors one factor.	The institution monitors neither factor.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	IRB Guidebook I, Institute of Medicine, "*Preserving the Public Trust. Accreditation and Human Research Participant Protection Programs."*			
Data Sources	Reports			
Notes	Examples of documents that may demonstrate compliance with this element include: minutes from IRB or R&D Committee or Quality Improvement Committee, quality assurance or improvement reports, internal or external audit or monitoring reports, investigator performance evaluations.			

Element INR7D	If gaps in performance are identified through any of its monitoring activities or other sources, the institution implemented corrective action (e.g., changes policy, procedure, communication, implements education or other such intervention) to improve.				
Weight (1-5)	3				
Scoring Guidelines	100%	75%	50%	0%	NA
	The institution implemented corrective action to address all identified performance gaps.	The institution implemented corrective action to address at least half of the identified performance gaps.	NA	The institution implemented corrective action on less than half of the identified performance gaps.	No identified performance gaps.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.103(a), 38CFR16.103(b)(5), 45CFR46.103(a), 45CFR46.103(b)(5), FWA, IRB Guidebook I				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality improvement reports, R&D Committee minutes, changes to policies and procedures, other documentation of action taken.				

Element INR7E	If gaps in performance were identified and corrective action implemented, the institution reassesses performance to assess the effectiveness of the action taken.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	NA
	The institution reassessed performance after one or more corrective actions were implemented.	NA	NA	No reassessment after corrective action (or no corrective action implemented.)	No identified performance gaps.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	FWA, IRB Guidebook I				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: minutes from IRB or R&D Committee or Quality Improvement Committee, quality assurance or improvement reports, internal or external audit or monitoring reports, investigator performance evaluations.				

Element INR7F	The institution tracks the following QI factors: 1. Identified need for improvement. 2. Action taken to improve. 3. Results of QI activities including pre- and post- evaluation measurement.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	The institution tracks all three factors.	NA	The institution tracks two factors.	The institution tracks less than two factors.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	FWA, IRB Guidebook I			
Data Sources	Reports			
Notes	Examples of documents that may demonstrate compliance with this element include: information systems query, database reports, log.			

Element INR7G	The institution evaluates its compliance with policies and procedures regarding the use of investigational devices. Evaluations address the following factors: 1. Storage. 2. Security. 3. Dispensing.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	NA
	Evaluations address three factors.	Evaluations address two factors.	Evaluations address one factor.	Evaluations address no factors.	The institution does not conduct investigational device research.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	21CFR812.140(a)(2), FDA Information Sheets – Medical Devices, FWA, IRB Guidebook I				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: minutes from IRB or R&D Committee or Quality Improvement Committee, quality assurance or improvement reports, internal or external audit or monitoring reports, investigator performance evaluations.				

Element INR7H	If areas of noncompliance in the use of investigational devices are identified, the institution implemented corrective action (e.g., changes policy, procedure, communication, implemented education, or other intervention) to restore compliance.				
Weight (1-5)	3				
Scoring Guidelines	100%	75%	50%	0%	NA
	The institution implemented corrective action to address all identified areas of noncompliance.	The institution implemented corrective action to address at least half of the identified areas of noncompliance.	NA	The institution implemented corrective action to address less than half of the identified areas of noncompliance.	No areas of noncompliance identified.
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions				
Regulatory Support	FWA, IRB Guidebook I, MPA				
Data Sources	Reports				
Notes	Examples of documentation that may demonstrate compliance with this element include: quality improvement reports, R&D Committee minutes, changes to policies and procedures, other documentation of action taken.				

INRII	**The institution educates institutional staff about, and holds them accountable for protecting the rights, safety and well being of human research participants.**

Requirement INR8	**The institution ensures that research investigators, research staff, IRB members and other individuals with responsibility for human subject protection have completed required training in human subject protection.**			
Element INR8A	Policies and procedures regarding education and training address the following: 1. Type and scope of human subject protection education and training that meets VA and Federal requirements. 2. Identification of the individuals for whom training is required in compliance with VA and Federal requirements. 3. Methods for confirming that individuals required to have training by VA and Federal requirements have met training requirements.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all three factors.	NA	NA	Policies and procedures address less than three factors.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.107(a)(b), 45CFR46.107(a)(b), 21CFR56.107(a)(b), DHHS Requirement, FWA A-7, FWA A-8, IRB Guidebook I, Policy Guidance			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB, R&D Committee and institution policies and procedures, memos or other notices about training and education.			
Element INR8B	The institution maintains a log or tracking system of required training received by investigators. The log or tracking system includes completion dates of approved training in human research protection.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	The institution tracks completion of investigator training.	NA	NA	The institution does not track completion of investigator training
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	FWA A-8			
Data Sources	Reports			
Notes	Examples of documents or methods the may demonstrate compliance with this element include: training logs, database reports, system queries, or other evidence of training accessible by investigator.			

Element INR8C	The institution maintains a log or tracking system of required training received by IRB members and other individuals with responsibility for human subject protections. The log or tracking system includes completion dates of approved training in human research protection for the following: 1. All IRB members. 2. All other individuals with responsibility for human research protection.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	The institution tracks completion of IRB members **and** other individuals training.	NA	The institution tracks completion of IRB members **or** other individuals training.	The institution does not track completion of training.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	FWA A-7, FWA A-8, IRB Guidebook I			
Data Sources	Reports			
Notes	Examples of documents or methods the may demonstrate compliance with this element include: training logs, database reports, system queries, or other evidence of training accessible by investigator.			

Element INR8D	The institution's research investigators have completed required training in human research protection.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	All research investigators have completed required training.	NA	NA	Not all research investigators have completed required training.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	FWA A-8, IRB Guidebook I, NIH Guidelines			
Data Sources	Reports			
Notes	Examples of documents or methods that may demonstrate compliance with this element include: training logs, database reports, system queries, or other evidence that all investigators have completed training.			

Element INR8E	The institution's IRB members and other individuals with responsibility for human research protection have completed required training in human research protection.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	All IRB members and other individuals have completed training.	NA	NA	Not all IRB members and other individuals have completed training.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	FWA A-7, IRB Guidebook I			
Data Sources	Reports			
Notes	Examples of documents or methods the may demonstrate compliance with this element include: training logs, database reports, system queries, or other evidence of training.			

Element INR8F	The institution provides guidance to investigators regarding development of consent forms and conduct of the consent process. The institution provides guidance in the following: 1. Developing consent form documents. 2. Conducting the informed consent process.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	The institution provides guidance on both factors.		The institution provides guidance in one factor.	The institution does not provide guidance regarding informed consent.
Scope of Review	NCQA evaluates this element once for the institution.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	M-3, Part I, Chapter 3, Appendix 9C, FDA Information Sheets – Guide to Informed Consent, IRB Guidebook III			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: institutional or IRB communications, investigator guidance and instructions.			

Topic Area **Individual IRB Structure and Operations (IRB)**

Rationale *Institutional Review Boards (IRB) are committees established to protect the rights and welfare of human research subjects through prospective and continuing review of research. IRB structure, composition and function must meet regulatory standards and be sufficient to allow for thorough and expert review of issues related to protecting the human subjects of research. This standard contains the requirements for IRB membership, written IRB policies and procedures and processes to provide adequate supervision of research.*

IRBI	**The IRB's structure and composition are appropriate to the amount and nature of research reviewed and meet regulatory requirements.**

Requirement IRB1	**The IRB has proper composition and the IRB has information about each IRB member.**			
Element IRB1A	The IRB maintains, or has access to the following information about each IRB member: 1. Name. 2. Earned degrees. 3. Representative capacity (e.g., physician, non-scientist, ethicist, community member, etc.). 4. Indications of experience, such as board certifications, licensures, certifications, etc. 5. For community members, past or present association with the VA (including academic affiliates). 6. For community members, confirmation that no part of the community member's immediate family is affiliated with the VA or its academic affiliates. 7. Documentation of the voting status of each member. 8. Documentation of alternate status.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	The IRB has access to all eight factors.	The IRB has access to seven factors.	The IRB has access to five factors.	The IRB has access to less than five factors.
Scope of Review	NCQA evaluates this element for each IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(3), 38CFR16.107(d), 38CFR16.115(a)(5), M-3, Part I, 9.09 g(1)(e)2, M-3, Part I, 9.09g(1)(e)1 a, M-3, Part I, 9.09 g(1)(e)1 b, M-3, Part I, 9.09g(1)(e)1 c, M-3, Part I, 9.09g(1)(e)1 d, 45CFR46.103(b)(3), 45CFR46.115(a)(5), 45CFR46.107(d), 21CFR56.115(a)(5), 21CFR56.107(d), FDA Information Sheets – Self Evaluation Checklist for IRB's, IRB Guidebook I B, MPA			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include; IRB member CVs, MPA member list, IRB member files.			

Element IRB1B	Consistent with VA and Federal regulations and policies, the IRB includes the following: 1. At least five members. 2. At least one member whose primary area of interest is non-scientific (e.g., lawyer, clergy or ethicist). 3. At least one member whose primary area of interest is scientific. 4. At least one member who does not have any association with the VA or affiliated university HRPP or who is part of the immediate family of a person who is affiliated with either organization. 5. Members of more than one profession. 6. Where university affiliate IRBs are used, the IRB has at least one member who is a VA representative.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	IRB includes all required members.	NA	NA	IRB includes less than all required members.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.107(a), 38CFR16.107(b), 38CFR16.107(c), 38CFR16.107(d), M-3, Part I, 3.01e(1)(c), 45CFR46.107(a), 45CFR46.107(b), 45CFR46.107(c), 45CFR46.107(d), 21CFR56.107(a), 21CFR56.107(b), 21CFR56.107(c), 21CFR56.107(d), FDA Information Sheets – IRB Membership, ICH Guidelines 3.2.1, IRB Guidebook I B, OHRP Common Findings and Guidance #52			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: MPA, IRB membership lists, IRB member CVs/bios.			
Element IRB1C	The IRB includes a diversity of membership based on consideration of race, gender, cultural background and sensitivity to such issues as community attitudes.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	IRB is diverse.	NA	NA	IRB is not diverse.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.107(a)(b), 45CFR46.107(a)(b), 21CFR56.107(a) (b), FDA Information Sheets – IRB Membership, ICH Guidelines 3.2, IRB Guidebook I, OHRP Common Findings & Guidance #52			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB membership lists, IRB member CVs/bios, interviews.			

Element IRB1D	Consistent with VA policy, VA IRBs must include the following members: 1. A Chair who holds a VA appointment. 2. At least one member from the R&D Committee. 3. Two or more members who are not already VA appointees nor directly connected with the R&D program within the institution.				
Weight (1-5)	4				
Scoring Guidelines	100%	75%	50%	0%	NA
	VA IRB includes all required members.	NA	NA	VA IRB includes less than all required members.	IRB Not VA
Scope of Review	NCQA evaluates this element once for the institution.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-3, Part I 3.01e(1)(a)				
Data Sources	Files				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB membership list, R&D Committee membership list, IRB Chair CV				

Requirement IRB2	The IRB meets regularly and with sufficient frequency, and members have sufficient information and time to review materials prior to the IRB meeting.			
Element IRB2A	The IRB meetings have the following arrangements: 1. Set meeting schedule. 2. Established timelines for receipt of protocol materials by the IRB office and distribution of materials to members.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	The IRB has a set meeting schedule and timeline.	NA	NA	The IRB does not have a set meeting schedule or timeline.
Scope of Review	NCQA evaluates this element for each IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	FDA Information Sheets – Self Evaluation Checklist for IRB's, OHRP Common Findings and Guidance #14, OHRP Guidelines for IRB Policies and Procedures			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB meeting schedule, IRB Minutes, instructions to investigators.			
Element IRB2B	IRB members receive meeting materials far enough in advance of the scheduled meeting to allow for sufficient review.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	IRB members receive materials with sufficient time for review.	NA	NA	IRB members do not have sufficient time for review.
Scope of Review	NCQA evaluates this element for each IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	FDA Information Sheets – Self Evaluation Checklist for IRB's, OHRP Common Findings and Guidance #14, OHRP Guidelines for Formulating Written IRB Policies and Procedures			
Data Sources	Reports, interviews			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB member interviews, quality assurance reports.			

Element IRB2C	For initial review, IRB members receive the following materials (if there is not a primary reviewer system): 1. Full protocol. 2. Informed consent form. 3. Any relevant merit review or grant applications. 4. Investigator's brochure (if applicable). 5. Advertisements or subject information (if applicable). 6. Subject surveys or questionnaires (if applicable).				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	IRB members receive all applicable materials.	NA	NA	IRB members receive less than all applicable materials.	IRB uses primary reviewer system.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	FDA Information Sheets – Self Evaluation Checklist for IRB's, OHRP Common Findings and Guidance #14, OHRP Guidelines for Formulating Written IRB Policies and Procedures.				
Data Sources	Materials, documented process, interview				
Notes	Examples of documents that may demonstrate compliance with this element include: sample meeting packet, staff instructions for preparing packets, interview with IRB coordinator.				

Requirement IRB3	The IRB systematically assigns reviewers to protocols prior to initial review (e.g., primary/secondary reviewer system), if applicable.				
Element IRB3A	The IRB systematically assigns review responsibility consistent with protocol content and reviewer expertise.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	IRB systematically assigns reviews consistent with protocol content and reviewer expertise.	NA	NA	IRB does not systematically assign reviews consistent with protocol content and reviewer expertise.	IRB does not use primary reviewer system.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.107(a), 45CFR46.107(a), 21CFR56.107(a), OHRP Common Findings & Guidance #15				
Data Sources	Reports, interviews				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, IRB policies and procedures.				
Element IRB3B	Primary reviewers receive the following materials: 1. Full protocol. 2. Informed consent form. 3. Any relevant merit review or grant applications. 4. Investigator's brochure (if applicable). 5. Advertisements or subject information (if applicable). 6. Subject surveys or questionnaires (if applicable).				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Primary reviewers receive all applicable materials.	NA	NA	Primary reviewers receive less than all applicable materials.	IRB does not use primary reviewer system.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	FDA Information Sheets – Self Evaluation Checklist for IRB's, OHRP Common Findings and Guidance # 14, #15, OHRP Guidelines for Formulating Written IRB Procedures				
Data Sources	Materials				
Notes	Examples of documents that may demonstrate compliance with this element include: staff instructions for preparing packets, sample primary reviewer packet.				

Element IRB3C	All IRB members receive at least the following materials: 1. Protocol summary. 2. Informed consent form. 3. Advertising material, if applicable				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	IRB members receive all applicable materials.	NA	NA	IRB members receive less than all applicable materials.	IRB does not use primary reviewer system.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	FDA Information Sheets – Self Evaluation Checklist for IRB's, ICH Guidelines, OHRP Common Finding and Guidance #15, OHRP Guidelines for Formulating Written IRB Procedures.				
Data Sources	Materials				
Notes	Examples of documents that may demonstrate compliance with this element include: sample IRB member meeting packet, staff instructions for preparing packets				

IRB II	The IRB systematically evaluates each research protocol to ensure adequate protection of human subjects in research.

Requirement IRB4	There are written policies and procedures, consistent with applicable VA and Federal requirements that describe IRB operations and functions.			
Element IRB4A	The IRB policies and procedures address the following investigator reporting requirements consistent with VA and Federal regulations: 1. Submitting proposed research for approval (or exemption from IRB review). 2. Submitting proposed changes in research for approval. 3. Submitting proposed changes in consent forms for approval. 4. Reporting deviations from approved protocol or other regulations and policies. 5. Reporting adverse events. 6. Reporting unanticipated problems involving risks to subjects. 7. Providing IRB required data for continuing review. 8. Submitting termination/completion reports.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Policies and Procedures address all eight factors.	NA	NA	Policies and Procedures address less than eight factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(3), 38CFR16.103(b)(4), 38CFR16.103(b)(5), 38CFR16.108, 45CFR46.103(b)(3), 45CFR46.103(b)(4), 45CFR46.103(b)(5), 45CFR46.108, 21CFR56.108, 21CFR312.66, FDA Information Sheets – Continuing Review after Study Approval, FDA Information Sheets – FAQ-IRB Procedures, ICH Guidelines 3.3.8, IRB Guidebook I B, III H, OHRP Common Findings and Guidance #22-24, OHRP Guidelines for Formulating Written IRB Procedures.			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidance/instructions.			

Requirement IRB5	The IRB reviews required and relevant information to evaluate research proposals during initial review and takes appropriate action.			
Element IRB5A	Based on its initial review, the IRB takes one of the following actions: 1. Approves proposed research. 2. Requires modifications (to secure approval). 3. Disapproves proposed research.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	The IRB takes one of three actions on each research proposal.	NA	NA	The IRB takes none of the three specified actions.
Scope of Review	NCQA evaluates this element for each IRB used. NCQA evaluates one year's IRB minutes or other documentation to assess compliance with this element.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.109(a), 45CFR46.109(a), 21CFR56.109(a), ICH Guidelines 3.1.2			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, IRB communications to investigators.			

Requirement IRB6	**The IRB uses information requested by the IRB, reports from investigators and other monitoring of ongoing research and requires changes as appropriate.**			
Element IRB6A	The IRB has policies and procedures for the monitoring of ongoing research during the period for which the research is authorized. Policies and procedures include consideration of the following: 1. Changes to the research. 2. Adverse event reports. 3. Safety reports, including IND, IDE, and MedWatch. 4. Protocol violations and/or deviations. 5. Investigator non-compliance.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all five factors.	Policies and procedures address four factors.	NA	Policies and procedures address less than four factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(4)(iii), 38CFR16.106(b)(5)(i). M-3, Part I, 9.09d, 45CFR46.103(b)(4)(iii), 45CFR46.106(b)(5)(i), 21CFR56.108(a)(3), 21CFR56.108(b)(2), ICH Guidelines 3.3.8, IRB Guidebook I D, OHRP Common Findings and Guidance #22-24, OHRP Guidelines for Formulating Written IRB Policies and Procedures			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB policies and procedures, instructions or training material for IRB members, IRB review forms or checklists.			

Element IRB6B	Whenever the IRB determines that the risks to subjects have changed after reviewing documentation obtained during the period for which the research is authorized, the IRB takes one of the following actions. The IRB decides that the research: 1. May continue. 2. May continue with modifications. 3. Must be suspended. 4. Must be terminated.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	The IRB takes one of four specified actions for each research study monitored.	NA	NA	IRB takes none of the four specified actions.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA reviews one year's IRB minutes or other documentation to assess compliance with this element.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.109(a), 38CFR16.109(e), 45CFR46.109(a), 45CFR46.109(e), 21CFR56.109(a), 21CFR56.109(f), FDA Information Sheets – Continuing Review after Study Approval, IRB Guidebook III H			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element may include: IRB minutes, IRB documentation, IRB communications to investigators			

Requirement IRB7	**The IRB uses required and relevant information to conduct continuing review of research at specified intervals and requires changes as appropriate.**			
Element IRB7A	The IRB has policies and procedures for the conduct of continuing review that include consideration of the following: 1. Changes to the research. 2. Adverse event reports. 3. Safety reports, including IND, IDE, and MedWatch. 4. Protocol violations and/or deviations. 5. Investigator non-compliance, including non-compliance with IRB requirements for frequency of periodic continuing review.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all five factors.	NA	NA	Policies and procedures address less than five factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(4), 38CFR16.103(b)(5), 45CFR46.103(b)(4), 45CFR46.103(b)(5), 45CFR46.109(e), 21CFR56.108(a), 21CFR56.109(f), IRB Guidebook III H, OHRP Common Findings and Guidance #5, #7, #16, OHRP Guidelines for Formulating Written IRB Policies and Procedures.			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, IRB guidance/instructions.			
Element IRB7B	The IRB has policies and procedures for the management of protocols with lapsed approval.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address lapsed approval.	NA	NA	Policies and procedures do not address lapsed approval.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(5), 38CFR16.109(e), 45CFR16.103(b)(5), 45CFR46.109(e), 21CFR56.108(a), 21CFR56.109(f)			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, IRB guidance/instructions.			

Element IRB7C	Based on its review of the information submitted at continuing review, the IRB decides one of the following. The research: 1. May continue. 2. May continue with modifications. 3. Must be suspended. 4. Must be terminated.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	The IRB takes one of the four specified actions for each continuing review.	NA	NA	The IRB does not take one of the four specified actions.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA reviews one year's IRB minutes or other documentation to assess compliance with this element.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.109(a)(e), 38CFR16.113, 45CFR46.109(a)(e), 45CFR46.113, 21CFR56.109(a)(f), 21CFR56.113, IRB Guidebook III H, OHRP Common Findings & Guidance #5, #7, #16, OHRP Guidelines for Formulating Written IRB Policies and Procedures			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, IRB communications to investigators.			

Requirement IRB8	The IRB conducts expedited review of research in accordance with VA and Federal policies and regulations.				
Element IRB8A	The IRB's policies and procedures for expedited review conform to VA and Federal policies and regulations and include the following: 1. Qualifications and experience criteria for IRB members to serve as designee(s) to the Chair for the conduct of expedited review. 2. Criteria for determining that research involves no more than minimal risk. 3. Criteria for determining that changes in previously approved research during the period for which the approval is authorized are minor. 4. Methods for advising IRB members of research approved through expedited review.				
Weight (1-5)	4				
Scoring Guidelines	100%	75%	50%	0%	NA
	IRB policies and procedures address all four factors.	IRB policies and procedures address three factors.	NA	IRB policies and procedures address less than three factors.	IRB does not conduct expedited review.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.110(b)(1), 38CFR16.110(b)(2), 38CFR16.110(c), M-3, Part I, 9.10, 45CFR46.110(b)(1), 45CFR46.110(b)(2), 45CFR46.110(c), 21CFR56.110(b)(1), 21CFR56.110(b)(2), 21CFR56.110(c), OHRP Common Findings and Guidance #17-21, OHRP Guidelines for Formulating Written IRB Procedures.				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB policies and procedures.				

Element IRB8B	The IRB policies and procedures for expedited review establish requirements for continuing review of research previously approved by the convened IRB. Expedited review is permitted **if one** of the following conditions are met: 1. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects. 2. No subjects have been enrolled and no additional risks have been identified. 3. The remaining research activities are limited to data analysis.				
Weight (1-5)	4				
Scoring Guidelines	100%	75%	50%	0%	NA
	IRB policies and procedures permit expedited continuing review only for the three specified conditions.	NA	NA	IRB policies and procedures permit expedited continuing review for other than the three specified conditions.	IRB does not conduct expedited continuing review.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	Federal Register, Vol. 63, No.216, 11/9/98				
Data Sources	Policy and procedure manual				
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures.				

Element IRB8C	The IRB policies and procedures may permit expedited review at continuing review if **all** of the following conditions are met: 1. The research is not conducted under an investigational new drug application or investigational device exemption. 2. Other categories of expedited review do not apply. 3. The IRB has determined at a convened meeting that the research involves no greater than minimal risk. 4. No additional risks have been identified.				
Weight (1-5)	4				
Scoring Guidelines	100%	75%	50%	0%	NA
	IRB policies and procedures only permit expedited continuing review if all four conditions met.	NA	NA	IRB policies and procedures permit expedited continuing review when less than four conditions met.	IRB does not conduct expedited continuing review.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	Federal Register, Vol. 63, No.216, 11/9/98				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures.				

Element IRB8D	The IRB conducts expedited review of protocols in conformance with its policies and procedures including: 1. The IRB Chair or qualified designee conducts expedited review. 2. Full convened IRB is notified of all expedited reviews.				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Element met in 100% of sampled files.	NA	NA	Element met in less than 100% of files.	IRB does not conduct expedited review.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA randomly samples 16 studies that include at least one expedited action, including initial review, continuing review, protocol amendments or consent form changes. If there are fewer than 16 such files in the sample, NCQA will review all active studies.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	OHRP Guidelines for Formulating Written IRB policies and Procedures				
Data Sources	Files				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation.				

Requirement IRB9	The IRB determines whether research involving human subjects is exempt from IRB review.				
Element IRB9A	The IRB policies and procedures for determining exempt status conform to VA and Federal regulations and include the following: 1. Definition of categories of research that are exempt from IRB review. 2. Process for determining exempt status.				
Weight (1-5)	4				
Scoring Guidelines	100%	75%	50%	0%	NA
	Policies and procedures address two factors.	NA	NA	Policies and procedures address less than two factors.	IRB does not exempt any research from review
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.101(b), M-3, Part I, 9.06bc, 45CFR46.101(b), 21CFR56.104, 21CFR56.105, MPA				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB or institutional policies and procedures.				
Element IRB9B	The institution or IRB makes determination of exempt status in accordance with VA policy and Federal regulations.				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Element met in 100% of sampled files	NA	NA	Element met in less than 100% of sampled files.	IRB does not exempt any research from review.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA reviews a random sample of 16 files determined exempt from review during the 12 months preceding the date of survey application. If there are fewer than 16 such files in the sample, NCQA will review all exempt files.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.101(b), M-3, Part I, 9.06bc, 45CFR46.101(b), 21CFR56.104, 21CFR56.105, MPA, OHRP Guidebook IV A				
Data Sources	Files				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB documentation, IRB communications, IRB minutes.				

Requirement IRB10	**The IRB determines the risk level of devices.**					
Element IRB10A	The IRB's policies and procedures for the review of research involving investigational devices address the following: 1. Determination of risk level is based on proposed use of the device and not the device alone. 2. Statements that the IRB may agree or disagree with the sponsor's assessment of significant risk or nonsignificant risk. 3. The process for notifying the Sponsor and investigator of the IRB decision of significant risk. 4. Review of significant risk device studies occurs only after an IDE is obtained by the sponsor. 5. Protocols involving significant risk devices do not qualify for expedited review.					
Weight (1-5)	2					
Scoring Guidelines	100%	75%	50%	0%	NA	
	Policies and procedures address all five factors.	Policies and procedures address four factors.	Policies and procedures address three factors.	Policies and procedures address less than three factors.	The institution does not conduct device research.	
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.					
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions					
Regulatory Support	21CFR812.66, FDA Information Sheets – SR/NSR Medical Device Studies, FDA Information Sheets – IRB Review of Medical Devices, IRB Guidebook V D, V B					
Data Sources	Documented process					
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures.					
Element IRB10B	The IRB determines the risk level of devices in accordance with VA and Federal policies and regulations.					
Weight (1-5)	4					
Scoring Guidelines	100%	75%	50%	0%	NA	ANR
	Element met in 100% of sampled device files reviewed.	NA	NA	Element met in less than 100% of sampled device files reviewed.	The institution does not conduct device research.	Applicable but not reviewed. No device studies reviewed.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA will randomly sample 16 active research files for review. Any device studies included in the sample will be used to assess compliance with this element.					
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions					
Regulatory Support	21CFR812.66, FDA Information Sheets – Medical Devices, IRB Guidebook V D, V B					
Data Sources	Files					
Notes	Examples of documents that may demonstrate compliance with this element include: IRB documentation, IRB communications, IRB minutes.					

IRB III	The IRB maintains documentation of its activities.

Requirement IRB11	The IRB documents discussions and decisions about research proposals and activities.			
Element IRB11A	Minutes of IRB meetings contain sufficient detail to show: 1. Attendance. 2. Approval of prior meeting minutes. 3. Actions taken by the IRB at the meeting. 4. The vote on actions, including the number of members voting for, against and abstaining. 5. Names of members abstaining. 6. Summary of the discussion of controverted issues and their resolution. 7. Determination of the frequency of continuing review of each research project based upon the degree of risk, as determined by the IRB.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	All IRB minutes reviewed contain all seven factors.	NA	IRB minutes in the first six months contain less than seven factors, but recent six months contain all seven factors.	IRB minutes in the most recent six months contain less than all seven factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA reviews one year's IRB minutes to assess compliance with this element.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.109(e), 38CFR16.115(a)(2), M-3, Part I, 9.09g(1)(b), 45CFR16.109(e), 45CFR46.115(a)(2), 21CFR56.109(f), 21CFR56.115(a)(2), FDA Information Sheets – Self Evaluation Checklist for IRB's , IRB Guidebook I, OHRP Common Findings and Guidance, OHRP Guidelines for Formulating Written IRB Policies and Procedures			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes.			

Element IRB11B	The IRB meeting minutes reflect the presence of a quorum at each recorded vote or for the entire meeting. Minutes document the following: 1. Circumstances in which members with conflicts of interest did not participate in the deliberations or voting. 2. A non-scientific member of the IRB was present during the entire meeting.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	All IRB minutes document two factors.	NA	IRB minutes from the most recent six months document two factors.	IRB minutes in the most recent six months document less than two factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA reviews one year's IRB minutes to assess compliance with this element.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.115(a)(2), M-3, Part I, 9.09b, 45CFR46.115(a)(2), 21CFR56.115(a)(2), FDA Information Sheets – Self Evaluation Checklist for IRB's. ICH Guidelines 3.2.3, IRB Guidebook III D, OHRP Common Findings and Guidance #8, #9, #10, #100, OHRP Guidelines for Formulating Written IRB Policies and Procedures.			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes.			

Element IRB11C	The IRB documents the following, if applicable: 1. Assessment of additional safeguards to protect vulnerable populations if entered as study subjects. 2. Results of expedited reviews. 3. The basis for allowing expedited review. 4. The basis for allowing a protocol to be exempt from IRB review. 5. The basis for allowing waiver or alteration of informed consent forms, the informed consent process, or documentation of consent. 6. The basis for allowing exceptions from the general requirements for obtaining informed consent before the use of a test article. 7. The basis for allowing exceptions from informed consent requirements in planned emergency research. 8. The determination of risk level of investigational devices.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	The IRB documents all applicable factors.	NA	NA	The IRB documents less than all applicable factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA reviews one year's IRB minutes or other forms of IRB documentation to assess compliance with this element.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.101(b), 38CFR16.110, 38CFR16.110(b), 38CFR16.111(b), 38CFR16.116(c), 45CFR46.101(b), 45CFR46.110(b), 45CFR46.111(b), 45CFR46.116(c), 21CFR50.23, 21CFR50.24, 21CFR56.104, 21CFR56.105, 21CFR56.110(b), 21CFR56.111(b), 21CFR812.66			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, files, other IRB documentation.			

Element IRB11D	The IRB documents the following findings: 1. Analysis of risk and benefits of research reviewed. 2. Assessment of proposed informed consent documents.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	The IRB documents two factors in 100% of reviewed materials.	NA	The IRB documents one factor in 100% of reviewed materials.	The IRB documents less than one factor in one or more reviewed files.
Scope of Review	NCQA evaluates this element for each IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.111(a)(2), 38CFR16.116, M-3, Part I, 9.09, M-3, Part I, 9.11,M-3, Part I, Chapter 3, Appendix 9C, 45CFR46.111(a)(2),45CFR46.116; 21CFR56.111(a)(2), IRB Guidebook III A/B			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, files, or other IRB documentation.			
Element IRB11E	IRB decisions are reported to the investigator and appropriate institutional officials.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	All IRB decisions are reported.	NA	NA	Less than all IRB decisions are reported.
Scope of Review	NCQA evaluates this element for each IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.109(d), 38CFR16.113, 45CFR46.109(d), 45CFR46.113, 21CFR56.109(e), 21CFR56.113, FDA Information Sheets – Self Evaluation Checklist for IRB's, ICH Guidelines 3.1.2, IRB Guidebook I, III H			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB communications.			

Element IRB11F	Documentation of IRB actions are forwarded to the R&D Committee (for both VAMC IRBs and affiliate IRBs).			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	All IRB actions reported to R&D.	NA	NA	Less than all IRB actions reported to R&D.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA reviews one year's IRB minutes to assess compliance with this element. NCQA reviews one year's R&D Committee minutes to assess compliance with this element.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	M-3, Part I, 3.01e			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB communications, R&D Committee minutes.			
Element IRB11G	When reviewing a research proposal with elements warranting special attention (e.g. placebos, challenge studies, radiation exposure, deviations from standards of care) the IRB documents its consideration of the appropriateness of, and rationale for, such elements.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Element met in 100% of applicable files reviewed.	NA	NA	Element not met in one or more applicable files reviewed.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA reviews one year's IRB minutes to assess compliance with this element. NCQA will select 5 cases from the minutes and ask for documentation on site.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	IRB Guidebook III A			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, files, and other IRB documentation.			

Requirement IRB12	The IRB retains required records for at least three years from study completion.			
Element IRB12A	The IRB retains records for a minimum of three years following the completion of the study, in accordance with VHA's Records Control Schedule, applicable FDA and DHHS regulations, or as required by sponsors.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Record retention meets regulatory requirements.	NA	NA	Record retention does not meet regulatory requirements.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.115(b), 45CFR46.115(b), 21CFR56.115(b)			
Data Sources	Interview, visual inspection			
Notes	Examples that may demonstrate compliance with this element include: IRB staff are able to state how long records are kept, IRB staff are able to demonstrate where files are kept and how long they are kept.			
Element IRB12B	The IRB makes records accessible for inspection and copying by authorized representatives of VA, including accreditors and appropriate Federal departments or agencies, at reasonable times and in a reasonable manner.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	100% of files requested by surveyors are accessible.	NA	NA	Less than 100% of files requested by surveyors are accessible.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.115(b), 45CFR46.115(b), 21CFR56.115(b)			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB documentation.			

Element IRB12C	IRB records are the property and the responsibility of the local research office and are maintained and/or stored as required to protect the privacy and confidentiality of subjects.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Records are stored in a secure environment.	NA	NA	Records are not stored in a secure environment.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.115(b), 45CFR46.115(b), 21CFR56.115(b)			
Data Sources	Interview, visual inspection			
Notes	Examples that may demonstrate compliance with this element include: IRB staff are able to state how records are kept, IRB staff are able to demonstrate where files are kept and state who has access to files.			

Element IRB12D	The IRB controls access to protocol files. The IRB can provide information on the following: 1. Who accessed the files with the exception of IRB and research office staff. 2. What files were accessed. 3. When the files were accessed. 4. For what purpose the files were accessed.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Information is available on four factors.	Information is available on three factors.	Information is available on two factors.	Information is available on less than two factors.
Scope of Review	NCQA reviews this element for <u>each</u> IRB used. The IRB is able to produce all requested files.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	38CFR16.111(a)(7), 38CFR16.115(b), 45CFR46.111(a)(7), 45CFR46.115(b), 21CFR56.111(a)(7), 21CFR56.115(b)			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB file access logs.			

Requirement IRB13	The IRB conducts quality assurance/quality improvement activities for IRB operation.				
Element IRB13A	The IRB or its designee evaluates the adequacy and effectiveness of its processes including: 1. Established timelines for receipt and distribution of protocol materials. 2. The system for primary reviewer assignment, if applicable. 3. Information considered at initial review. 4. Information considered while monitoring ongoing research. 5. Information considered at continuing review.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	
	The IRB evaluates all applicable factors.	The IRB evaluates three factors.	The IRB evaluates two factors.	The IRB evaluates less than two factors.	
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	FDA Information Sheets – Self Evaluation Checklist for IRB's, IRB Guidebook I B, OHRP Common Findings and Guidance #14, #15				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality assurance reports, IRB minutes, correspondence.				
Element IRB13B	The IRB or its designee evaluates its compliance with VA and Federal regulations and the institution's policies and procedures for informed consent including the following areas, if applicable: 1. Granting waivers or alterations of informed consent documents or the informed consent process. 2. Granting exceptions from the general requirements for obtaining consent before the use of a test article. 3. Granting exceptions to informed consent in planned emergency research.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	NA
	The IRB evaluates all applicable factors.	NA	NA	The IRB evaluates less than all applicable factors.	The IRB does not grant waivers, alterations or exceptions.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	IRB Guidebook I B				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality assurance reports, IRB minutes, correspondence.				

Element IRB13C	The IRB or its designee evaluates compliance with VA and Federal regulations and the institution's policies and procedures for the conduct of expedited review.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	NA
	IRB evaluates compliance.	NA	NA	IRB does not evaluate compliance.	The IRB does not conduct expedited review.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	IRB Guidebook I B				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality assurance reports, IRB minutes, correspondence.				
Element IRB13D	The IRB or its designee evaluates compliance with VA and Federal regulations and the institution's policies and procedures for determining exempt status.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	NA
	The IRB evaluates compliance.	NA	NA	The IRB does not evaluate compliance.	The IRB does not exempt protocols from IRB review.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	IRB Guidebook I B				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality assurance reports, IRB minutes, correspondence.				
Element IRB13E	The IRB or its designee evaluates compliance with VA and Federal regulations and the institution's policies and procedures for determining the risk level of devices.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	NA
	The IRB evaluates compliance.	NA	NA	The IRB does not evaluate compliance.	The IRB does not conduct device research.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	IRB Guidebook I B				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality assurance reports, IRB minutes, correspondence.				

Element IRB13F	If deficiencies are identified through the evaluations, the IRB implements corrective actions.				
Weight (1-5)	3				
Scoring Guidelines	100%	75%	50%	0%	NA
	The IRB implements corrective action for all identified deficiencies.	NA	The IRB implements corrective action for at least half of all identified deficiencies.	The IRB implements corrective action for less than half of all identified deficiencies.	No deficiencies identified.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	IRB Guidebook I B				
Data Sources	Reports				
Notes	Examples of documents that may demonstrate compliance with this element include: quality assurance reports, IRB minutes, correspondence.				

Topic Area **Consideration of Risks and Benefits (CRB)**

Rationale *All research should be designed to maximize possible benefits and minimize possible harms to participants. When a research proposal does not have the proper balance of risks and benefits, it should not be approved. One of the major responsibilities of the IRB is to assess the risks and benefits of the proposed research and to put in place safeguards that minimize the risks of harms to subjects. This standard contains the requirements for IRB actions related to assessment and balancing of risks and benefits.*

CRBI	**The IRB systematically evaluates risks and anticipated benefits as part of the initial review and continuing review of the research.**

Requirement CRB1	**The IRB has procedures for initial and continuing review of the risks and benefits of research.**			
Element CRB1A	Procedures for the initial and continuing review of the risks and benefits of research include the following: 1. Identification of the risks associated with research. 2. Assessment of whether risks have been minimized. 3. Determination of the level of risks of the research (e.g., minimal, greater than minimal). 4. Identification of the probable individual and societal benefits of the research. 5. Determination that risks are reasonable in relation to the benefits to subjects and the knowledge to be gained. 6. Determination of interval for continuing review based on the level of risk.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Procedures address all six factors.	Procedures address five factors.	Procedures address four factors.	Procedures address less than four factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(4), 38CFR16.111(a)(1), 38CFR16.111(a)(1)(2), 38CFR16.111(a)(2), M-3, Part I, 9.09(a)(1), 45CFR46.111(a)(1)(2), 45CFR46.111(a)(2), 21CFR56.111(a)(1)(2), 21CFR56.111(a)(2), IRB Guidebook III A, III H			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB policies and procedures, reviewer evaluation tools.			

Requirement CRB2	The IRB consistently identifies and analyzes potential sources of risk and the measures to minimize risk.			
Element CRB2A	The IRB's evaluation of research proposal risk includes consideration of the following: 1. Study design. 2. Scientific rationale. 3. Procedures to minimize risk. 4. Process for monitoring and reporting adverse events. 5. Presence of a Data Safety Monitoring Board (DSMB), if applicable. 6. Scientific training and qualifications of investigators and research staff. 7. Human subject protection training of investigators and research staff.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	Documentation of IRB evaluation of risks exists in IRB minutes or other IRB documentation for all applicable factors in 100% of sampled files.	The IRB Chair and IRB members articulate the process of risk evaluation by the IRB.	Evidence exists in the research protocol that the information was available to the IRB for evaluation in 100% of applicable sampled files.	At least one sampled protocol file lacks evidence of IRB evaluation of an applicable factor.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of submitted information about each factor in the protocol file. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.111(a)(1), 38CFR16.111(a)(6), M-3, Part I, 9.09, 45CFR46.111(a)(1), 45CFR46.111(a)(6), 21CFR56.111(a)(1), 21CFR56.111(a)(6), FWA A-8, ICH Guidelines 3.1.3, ICH Guidelines 5.5.2, IRB Guidebook III A, IV A			
Data Sources	Files, materials, interviews			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, interview with IRB Chair and members, protocol.			

Element CRB2B	The IRB documents its evaluation of research proposal risk, including evaluation of the following: 1. Study design. 2. Scientific rationale. 3. Procedures to minimize risk. 4. Process for monitoring and reporting adverse events. 5. Presence of a Data Safety Monitoring Board (DSMB), if applicable. 6. Scientific training and qualifications of investigators and research staff. 7. Human subject protection training of investigators and research staff.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	Documentation exists in IRB minutes or other IRB documentation of IRB evaluation of all applicable factors in 100% of sampled files.	NA	NA	At least one sampled protocol file lacks documentation of IRB evaluation of an applicable factor.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited			
Regulatory Support	38CFR16.111(a)(1), 38CFR16.111(a)(6), M-3, Part I, 9.09, 45CFR46.111(a)(1), 45CFR46.111(a)(6), 21CFR56.111(a)(1), 21CFR56.111(a)(6), FWA A-8, ICH Guidelines 3.1.3, ICH Guidelines 5.5.2, IRB Guidebook III A, IV A			
Data Sources	Files, materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation.			

Element CRB2C	The IRB considers the inclusion of vulnerable subjects in research, where applicable. Consideration includes the following: 1. Category of vulnerability of the proposed study population. 2. Additional safeguards planned to protect the rights and welfare of potentially vulnerable subjects.				
Weight (1-5)	5				
Scoring Guidelines	100%	75%	50%	0%	NA
	Documentation of IRB consideration of the two factors exists in IRB minutes or other IRB documentation in 100% of applicable sampled protocol files.	The IRB Chair and IRB members articulate the process for IRB consideration of the inclusion and protection of vulnerable subjects.	Evidence exists in the research protocol that information about both factors was available to the IRB for consideration in 100% of applicable sampled protocol files.	At least one sampled protocol files lacks evidence of IRB consideration of an applicable factor.	No protocol files reviewed included vulnerable populations.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews applicable files for evidence of IRB consideration, or for presence of submitted information about each factor in the protocol file. If there are fewer than 16 such files in the sample, NCQA will review all active studies.				
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.111(a)(3), 38CFR16.111(b), M-3, Part I, 9.09(a)(3), M-3, Part I, 9.09(a)(8), 45CFR46.111(a)(3), 45CFR46.111(b), 21CFR56.111(a)(3), 21CFR56.111(b), IRB Guidebook III C, VI				
Data Sources	Files, materials, interviews				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, interview with IRB Chair and members, protocol.				

Element CRB2D	The IRB documents its consideration of the inclusion of vulnerable subjects where applicable, in research, including the following: 1. Category of vulnerability of the proposed study population. 2. Additional safeguards planned to protect the rights and welfare of potentially vulnerable subjects.				
Weight (1-5)	1				
Scoring Guidelines	100%	75%	50%	0%	
	Documentation exists in IRB minutes or other IRB documentation for both factors in 100% of applicable sampled protocol files.	NA	NA	At least one sampled protocol file lacks documentation of IRB evaluation of an applicable factor.	
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews applicable files for evidence of IRB consideration. If there are fewer than 16 such files in the sample, NCQA will review all active studies.				
Accreditation	0% ⇒ Accreditation no greater than Accredited				
Regulatory Support	38CFR16.111(a)(3), 38CFR16.111(b), M-3, Part I, 9.09(a)(3), M-3, Part I, 9.09(a)(8), 45CFR46.111(a)(3), 45CFR46.111(b), 21CFR56.111(a)(3), 21CFR56.111(b), IRB Guidebook III C, VI				
Data Sources	Files, materials				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation.				

Element CRB2E	The IRB distinguishes the risks of research activities from the risk of therapeutic activities (when applicable).				
Weight (1-5)	4				
Scoring Guidelines	100%	75%	50%	0%	NA
	Documentation exists that the IRB distinguishes research risk from therapeutic activities risk in 100% of applicable sampled protocol files.	The IRB Chair and IRB members articulate the process for the IRB distinguishing research risk from therapeutic activities risk.	Evidence exists in the research protocol that distinguishes research risk from therapeutic risk consideration in 100% of applicable sampled protocol files.	At least one applicable sampled protocol file lacks evidence distinguishing research risk from therapeutic risk.	No protocol files reviewed included therapeutic activities.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews applicable files for evidence of IRB consideration, or for presence of submitted information in the protocol file.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.111(a)(2), 45CFR56.111(a)(2), 21CFR56.111(a)(2), IRB Guidebook III A				
Data Sources	Materials, interview, files				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, interview with IRB Chair and members, protocol.				

Element CRB2F	The IRB documents its distinction of the risks of research activities from the risk of therapeutic activities (when applicable).			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	Documentation of the IRB distinction of research risk from therapeutic activities risk exists in IRB minutes or other IRB documentation in 100% of applicable sampled protocol files.	NA	NA	At least one applicable sampled file lacks documentation of IRB distinction of research risk from therapeutic risk.
Scope of Review	NCQA evaluates this element for each IRB used. NCQA selects a random sample of 16 active research studies and reviews applicable files for evidence of IRB consideration. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	38CFR16.111(a)(2), 45CFR56.111(a)(2), 21CFR56.111(a)(2), IRB Guidebook III A			
Data Sources	Materials, files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation.			

Element CRB2G	The IRB considers the following types of risk: 1. Physical 2. Psychological 3. Social 4. Economic			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Documentation exists of IRB consideration of the four factors in IRB minutes or other IRB documentation in 100% of sampled protocol files.	The IRB Chair and IRB members articulate the process of IRB consideration of the four factors.	Evidence exists in research protocols that the information was available to the IRB for consideration.	At least one sampled protocol file lacks evidence of IRB consideration of one of the four factors.
Scope of Review	NCQA evaluates this element for each IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of each factor in the protocol file. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	IRB Guidebook III A			
Data Sources	Materials, interview, files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, interview with IRB Chair and members, protocol.			

Element CRB2H	The IRB documents its consideration of the following types of risk: 1. Physical 2. Psychological 3. Social 4. Economic			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	Documentation exists in IRB minutes or other IRB documentation of IRB consideration of all four factors in 100% of sampled protocol files.	NA	NA	At least one sampled protocol file lacks documentation of IRB consideration of one factor.
Scope of Review	NCQA evaluates this element for each IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	IRB Guidebook III A			
Data Sources	Materials, files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation.			

Element CRB2I	The IRB determines the interval for continuing review appropriate to the degree of risk (at least once per year) for each protocol reviewed.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	Element met in 100% of sampled protocol files.	NA	NA	Element met in less than 100% of sampled protocol files.
Scope of Review	NCQA evaluates this element for each IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.109(e), 45CRF46.109(e), 21CFR56.109(e), IRB Guidebook III H			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, reviewer tools, communications to investigators.			

Requirement CRB3	The IRB evaluates each research proposal to identify the probable benefits of the research.			
Element CRB3A	The IRB evaluates each research proposal to identify the probable benefits of the research.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Documentation exists in IRB minutes or other IRB documentation of IRB evaluation of the probable benefits in 100% of sampled protocol files.	The IRB Chair and IRB members articulate the process of IRB evaluation of the probable benefits of research.	Evidence exists in research protocols that the information was available to the IRB for evaluation in 100% of sampled files.	At least one sampled protocol file lacks evidence of IRB evaluation of the probable benefits.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of the element in the protocol file. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.111(a)(2), M-3, Part I, 9.09 (2), 45CFR46.111(a)(2), 21CFR56.111(a)(2), IRB Guidebook III A.			
Data Sources	Files, materials, interview			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB documentation, IRB minutes, interview with IRB Chair and members, protocol.			
Element CRB3B	The IRB considers the importance of the knowledge that may be reasonably expected to result from the research.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Documentation exists in IRB minutes or other IRB documentation of IRB consideration of the importance of the research in 100% of sampled protocol files.	The IRB Chair and IRB members articulate the process of IRB consideration of the importance of the research.	Evidence exists in research protocols that the information was available to the IRB for consideration in 100% of sampled protocol files.	At least one sampled protocol file lacks evidence of IRB consideration of the importance of research.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of submitted information about the element in the protocol file. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.111(a)(2), M3, Part I, 9.09 (2) (b), 45CFR46.111(a)(2), 21CFR56.111(a)(2), IRB Guidebook III A.			
Data Sources	Materials, interview, files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation, interview with IRB Chair and members, protocol.			

Element CRB3C	The IRB documents its evaluation of the benefits of research, including the following: 1. The probable benefits to the subjects. 2. The importance of the knowledge that may be reasonably expected to result from the research.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	Documentation exists in IRB minutes or other IRB documentation of IRB evaluation of the two factors in 100% of sampled protocol files.	NA	NA	At least one sample protocol file lacks documentation of the IRB evaluation of one factor.
Scope of Review	NCQA evaluates this element for each IRB used. NCQA selects a random sample of 16 active research studies and reviews files for documentation of IRB consideration. If there are fewer than 16 such studies in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support	38CFR16.111(a)(2), M3, Part I, 9.09 (2) (b), 45CFR46.111(a)(2), 21CFR56.111(a)(2), IRB Guidebook III A.			
Data Sources	Materials, interview, files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation.			

Requirement CRB4	The IRB weighs the risks to subjects in relation to anticipated benefits.			
Element CRB4A	The IRB approves research only when it determines that the risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Documentation exists in IRB minutes or other documentation that the IRB determined risks are reasonable in relation to anticipated benefits.	NA	NA	At least one sampled protocol file lacks documentation that the IRB determined risks are reasonable in relation to anticipated benefits.
Scope of Review	NCQA evaluates this element for each IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of submitted information about the element in the protocol file. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.111(a)(2), M3, Part I, 9.09 (2), 45CFR46.111(a)(2), 21CFR56.111(a)(2), IRB Guidebook III A.			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation.			

Requirement CRB5	The IRB continually evaluates the risks and benefits of protocols.			
Element CRB5A	The IRB continually reviews information on sources of risks and benefits of the research. The IRB reviews the following: 1. Serious adverse event reports from investigators. 2. Sponsor safety reports (e.g., IND, IDE, or MedWatch reports). 3. Amended or updated Investigator Brochures. 4. Changes to the research, including amendments to the protocol. 5. New information available regarding the research project that may change the risk/benefit ratio. 6. Research findings to date, including summary of subject experiences (benefits, adverse reactions) and summary of DSMB meetings (if applicable). 7. Reports of injuries to subjects. 8. Unanticipated problems involving risks to subjects. 9. Subjects withdrawn and the reasons for withdrawal.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	IRB reviewed all nine factors when applicable in 100% of sampled protocol files.	NA	NA	IRB reviewed less than nine factors in 100% of sampled protocol files.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.103(b)(4)(iii), 38CFR16.103(b)(5), 38CFR16.103(b)(5)(i), 45CFR46.103(b)(4)(iii), 45CFR46.103(b)(5), 45CFR46.103(b)(5)(i), 21CFR56.103(b)(4)(iii), 21CFR56.103(b)(5)(i), 21CFR56.108(b), FDA Information Sheets – Continuing Review After Study Approval, FDA Information Sheets – Self Evaluation Checklist for IRB's, IRB Guidebook III H, OHRP Guidelines for Formulating Written IRB Policies and Procedures			
Data Sources	Materials, files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, IRB documentation.			

Topic Area **Recruitment and Subject Selection (RSS)**

Rationale *Because research frequently poses risks of harm and the possibility of benefit, it is necessary to distribute potential risks and benefits fairly. Special protections may be necessary for groups that have been discriminated against in the past, who are vulnerable to manipulation, or unable to freely consent. IRBs must assure that procedures for selecting research subjects are fair and that recruitment methods are acceptable. This standard outlines the expected processes that IRBs must use to ensure that research participants are identified and recruited properly.*

RSSI	**The IRB systematically evaluates recruitment practices.**

Requirement RSS1	**The IRB ensures that recruitment practices for proposed research are acceptable.**			
Element RSS1A	The IRB's policies and procedures define acceptable recruitment practices, consistent with regulatory guidance, as applied to the following activities: 1. Payment to subjects. 2. Advertisements. 3. Compensation to investigators, physicians and other health care providers for identifying and/or enrolling subjects.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all three factors.	Policies and procedures address two factors.	NA	Policies and procedures address less than two factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited			
Regulatory Support	M-3, Part I, 9.13, FDA Information Sheets – Recruiting Study Subjects, HHS-IGR, ICH Guidelines 5.8.3, IRB Guidebook III G, IV I			
Data Sources	Documented Process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, instructions to investigators.			

Element RSS1B	The IRB considers whether proposed subject recruitment methods, advertising materials and subject payment arrangements create undue influence to participate. The IRB reviews the following methods used to recruit potential subjects: 1. The nature or amount of the compensation offered to subjects for participation in research. 2. Proposed advertisements.				
Weight (1-5)	4				
Scoring Guidelines	100%	75%	50%	0%	NA
	Information about all applicable factors are present in 100% of sampled protocol files.	The IRB Chair and IRB members articulate the process of IRB consideration of proposed subject recruitment methods	Evidence exists that the information was available to the IRB for consideration in 100% of sampled protocol files.	Protocol states compensation will occur or advertising will be done, but no ad exists in the file nor is compensation detailed in 100% of sampled protocol files.	Study uses no advertisements or subject compensation.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of submitted information about each factor in the protocol files.				
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions				
Regulatory Support	M-3, Part I, 9.13b(3), FDA Information Sheets – Recruiting Study Subjects, ICH Guidelines 3.1.8, IRB Guidebook III G, IV I				
Data Sources	Files				
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, communications to investigators, protocol files.				

Requirement RSS2	The IRB systematically evaluates subject selection practices to ensure that the risks, burdens and benefits of research are equitably distributed.			
Element RSS2A	The IRB has policies and procedures for evaluating protocols regarding the equitable selection of subjects, which include consideration of the following: 1. Purposes of research. 2. Setting in which research occurs. 3. The scientific and ethical justification for including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. 4. The scientific and ethical justification for excluding classes of persons who might benefit from the research.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all four factors.	Policies and procedures address three factors.	Policies and procedures address two factors.	Policies and procedures address less than two factors.
Scope of Review	NCQA evaluates this element for each IRB used.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited			
Regulatory Support	38CFR16.111(a)(3), 38CFR16.111(b), M-3, Part I, 9.09a(3), M-3, Part I, 9.09a(8), 45CFR46.111(a)(3), 45CFR46.111(b), 21CFR56.111(a)(3), 21CFR56.111(b), IRB Guidebook III C, VI			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB policies and procedures.			

Element RSS2B	The IRB considers subject selection criteria in its review of research to ensure that subject selection criteria are appropriate to the purposes of research, consistent with VA and DHHS policies, and fairly distribute the burdens, risks and benefits of the research. The IRB evaluates the following: 1. The purpose of the research. 2. The burdens and risks of the research. 3. Potential benefits of the research. 4. Inclusion criteria. 5. Exclusion criteria.			
Weight (1-5)	3			
Scoring Guidelines	100%	75%	50%	0%
	Information about all five factors is present in 100% of sampled protocol files.	The IRB chair and IRB members articulate the process of IRB consideration of subject selection criteria.	Evidence exists that the information was available to the IRB for consideration in 100% of sampled protocol files.	No evidence exists in any form of IRB consideration of the element in less than 100% of sample protocol files.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of submitted information about each factor in the protocol files. If there are fewer the 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.111(a)(2), 38CFR16.111(a)(3), M-3, Part I, 9.09a(3), 45CFR46.111(a)(2), 45CFR46.111(a)(3), 21CFR56.111(a)(2), 21CFR56.111(a)(3), HHS-IGR, IRB Guidebook III C			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, reviewer evaluation tools, protocol files.			

Element RSS2C	The IRB considers subject enrollment at continuing review. The IRB considers whether recruitment methods, enrollment procedures and selection criteria fairly distribute the burdens, risks and benefits of research by evaluating the following: 1. Number of subjects entered into the study. 2. Gender of subjects entered into the study. 3. Minority status of subjects entered into the study. 4. Number of children entered into the study. 5. Number of women entered into the study. 6. If applicable, number of potentially vulnerable subjects entered into the study, including prisoners, pregnant women, economically and educationally disadvantaged, decisionally impaired, and homeless people.			
Weight (1-5)	3			
Scoring Guidelines	100%	75%	50%	0%
	Information about all applicable factors are present in 100% of sampled protocol files.	The IRB Chair and IRB members articulate the process of IRB consideration of the applicable factors for subject enrollment.	Evidence exists that the information was available to the IRB for consideration in 100% of sampled protocol files.	No evidence exists in any form of IRB consideration of the element in less than 100% of sampled protocol files.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of submitted information about each factor in the protocol files. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	FDA Information Sheets – Self Evaluation Checklist for IRB's, IRB Guidebook III H , OHRP Guidelines for Formulating Written IRB Policies and Procedures			
Data Sources	Files, system query			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, information provided by investigators, protocol list, protocol files.			

Topic Area **Privacy and Confidentiality (PCF)**

Rationale *Violation of a research subject's privacy may lead to significant harms such as loss of work, embarrassment, loss of benefits and loss of dignity. IRBs must determine that proposed research has adequate provisions to protect the privacy of human subjects and maintain the confidentiality of the data. IRBs must understand and consider risks of harm from loss of confidentiality, and methods to reduce the risk of breach of confidentiality. This standard outlines requirements for the protection of privacy and confidentiality.*

PCFI	**The IRB systematically evaluates the protection of privacy and confidentiality in proposed research.**

Requirement PCF1	**The IRB systematically evaluates research proposals for provisions to protect privacy and confidentiality.**			
Element PCF1A	The IRB provides investigators with policies and procedures for preserving subject privacy and confidentiality. The policies and procedures cover the following: 1. Methods used to obtain information about subjects. 2. Methods used to obtain information about individuals who may be recruited to participate in studies. 3. Nature of information that may be sought. 4. Use of personally identifiable records. 5. Methods to protect the confidentiality of research data that may include such measures as coding, removal of identifying information, limiting access to data, use of Certificates of Confidentiality or other effective methods. 6. The investigator's disclosures to participants about confidentiality. 7. Determination of whether a Federal Certificate of Confidentiality should be obtained.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all seven factors.	Policies and procedures address five factors.	Policies and procedures address three factors.	Policies and procedures address less than three factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions.			
Regulatory Support	38CFR16.111(a)(7), M-3, Part I, 9.09a(7), M-3, Part I, 9.14(a)(c), 45CFR46.111(a)(7), 21CFR56.111(a)(7), FDA Information Sheets – Guide to Informed Consent, IRB Guidebook III D			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, instructions to investigators.			

Element PCF1B	The IRB's evaluation of research proposals includes determining whether privacy and confidentiality are protected in the following: 1. Methods used to identify and recruit participants. 2. Methods to obtain information about participants. 3. Provisions for protecting the confidentiality of research data, including, where appropriate, Certificates of Confidentiality.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	IRB minutes or other IRB documentation show evidence of the IRB evaluation of all applicable factors in 100% of sampled protocol files.	The IRB Chair and IRB members articulate the process of IRB evaluation of all applicable factors.	Evidence exists in research protocols that the information was available for IRB consideration of all applicable factors in 100% of sampled protocol files.	At least one sampled protocol file lacks evidence of IRB evaluation of an applicable factor.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration, or for presence of submitted information about each factor in the protocol files. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.111(a)(7), M-3, Part I, 9.09a(7), 45CFR46.111(a)(7), 21CFR56.111(a)(7), IRB Guidebook III D			
Data Sources	Files, materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB documentation, IRB minutes.			

Element PCF1C	The IRB documents its evaluation of research proposals for protection of privacy and confidentiality. Documentation includes the following: 1. Methods used to identify and recruit participants. 2. Methods to obtain information about participants. 3. Provisions for protecting the confidentiality of research data, including, where appropriate, Certificates of Confidentiality.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	Documentation of IRB evaluation of all applicable factors exists in IRB minutes or other IRB documentation in 100% of sampled protocol files.	NA	NA	At least one sampled protocol file lacks documentation of IRB evaluation of an applicable factor.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA selects a random sample of 16 active research studies and reviews files for evidence of IRB consideration. If there are fewer than 16 such files in the sample, NCQA will review all active studies.			
Accreditation	0% $\Rightarrow$ Accreditation no greater than Accredited			
Regulatory Support	38CFR16.111(a)(7), M-3, Part I, 9.09a(7), 45CFR46.111(a)(7), 21CFR56.111(a)(7), IRB Guidebook III D			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB documentation, IRB minutes, checklists.			

Topic Area **Informed Consent (ICS)**

Rationale *Informed consent is critical to the protection of human research subjects. It is central to enabling participants to determine if they are willing to accept the risks of the research in order to gain the potential benefits or to support the development of new knowledge. For informed consent to take place, research participants need to be: 1) capable of deciding whether to participate; 2) adequately informed about the risks and benefits of participation; 3) able to understand the information; and 4) free to make a voluntary decision to participate. This standard outlines the requirements for methods to permit HRPPs and IRBs to assess whether the informed consent process is adequate.*

ICSI	**The IRB assures that prospective human subjects give valid informed consent.**

Requirement ICS1	**The IRB has policies and procedure for the process of obtaining informed consent from subjects or their legally authorized representatives and evaluates research proposals for compliance.**			
Element ICS1A	IRB policies and procedures describe the following: 1. The IRB has the authority to observe the consent process. 2. Who, under VA policy, state and local law, may serve as a legally authorized representative for subjects determined to be incapable of making an autonomous decision. 3. Who is eligible to inform the prospective subject about all aspects of the trial and conduct the informed consent process.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all three factors.	Policies and procedures address two factors.	NA	Policies and procedures address less than two factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.109(e), M-3, Part I, 9.11a, M-3, Part I, 9.12a(1), 45CFR46.109(e), 21CFR56.109(f), FDA Information Sheets – FAQ 39, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			

Element ICS1B	The IRB has policies and procedures that require investigators to obtain consent prior to entering a subject into a study and the conduct of any procedures required by the protocol, unless consent is waived by the IRB.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.111(a)(4), 38CFR16.116, 45CFR46.111(a)(4), 45CFR46.116, 21CFR50.20, 21CFR56.111(a)(4), ICH Guidelines 4.8			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			
Element ICS1C	The IRB has policies and procedures for evaluating the research plan for conducting the informed consent process with the following considerations: 1. Assessing the subject's capacity to consent to a research protocol, if applicable. 2. Ensuring that information is given to the subject, or their legally authorized representative, in a language that is understandable to the subject or representative. 3. Providing the prospective subject or the legally authorized representative sufficient opportunity to consider whether or not to participate. 4. Ensuring that subjects give consent without coercion or undue influence.			
Weight (1-5)	3			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all four factors.	NA	Policies and procedures address three factors.	Policies and procedures address less than three factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116, 45CFR46.116, 21CFR50.20, ICH Guidelines 4.8, IRB Guidebook IIIB			
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			

Requirement ICS2	The IRB has policies and procedures that define required content for informed consent forms.			
Element ICS2A	The IRB requires that consent forms include all the basic elements of information as set forth in VA and other Federal regulations.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for each IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116(a)(1-8), 45CFR46.116(a)(1-8), 21CFR50.25(a)(1-8),FDA Information Sheets – Guide to Informed Consent, FWA A-5, ICH Guidelines 4.8.5, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions, template consent.			
Element ICS2B	The IRB requires that consent forms include (when applicable) the additional elements of information as set forth in VA and other Federal regulations.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for each IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116(b)(1-6), 45CFR46.116(b)(1-6), 21CFR50.25(b)(1-6), FDA Information Sheets – Guide to Informed Consent, FWA A-5, ICH Guidelines 4.8.5, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions, template consent.			
Element ICS2C	The IRB requires all information concerning payment to subjects, including the amount and schedule of payments, be included in the informed consent document.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for each IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	M-3, Part I, 9.13b(2), ICH Guidelines 3.1.9			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions, template consent.			

Element ICS2D	The IRB requires the consent form to contain information in language understandable to the subject or the legally authorized representative. 1. The appropriate reading level of consent forms is defined, based on the potential population. 2. Validated translations of consent forms are available for non-English-speaking subjects, if applicable.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address two factors.	NA	NA	Policies and procedures address less than two factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116, 45CFR46.116, 21CFR50.20, FDA Information Sheets – Guide to Informed Consent, FWA A-5, ICH Guidelines 4.8.5, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			
Element ICS2E	The IRB prohibits any informed consent, whether oral or written, from including any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116, 45CFR46.116, 21CFR50.20, FDA Information Sheets – Guide to Informed Consent, FWA A-5, ICH Guidelines 4.8.5, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			

Element ICS2F	The IRB requires the content of consent forms to be consistent with state laws regarding content (if applicable).				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.	State laws do not address consent content.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.116(e), 45CFR46.116(c), 21CFR50.25(c)FDA Information Sheets – Guide to Informed Consent, FWA A-5, ICH Guidelines 4.8.5, IRB Guidebook III B				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.				

Requirement ICS3	**The IRB ensures that consent forms contain all required content.**			
Element ICS3A	IRB approved consent forms include all the basic elements of information as set forth in VA and other Federal regulations. 1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental. 2. A description of any reasonably foreseeable risks or discomforts to the subject. 3. A description of any benefits to the subjects or to others which may reasonably be expected from the research. 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and notes (if applicable) the possibility that the FDA may inspect the records. 6. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained. 7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	Information about all eight factors are present in 100% of sampled protocol files.	NA	NA	Information about less than all eight factors are present in less than 100% of sampled protocol files.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA will review a random sample of 16 files with written consent forms. If there are fewer than 16 such files in the sample, NCQA will review all files with written consent forms.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116(a)(1-8), M-3, Part I, Appendix 9C, 45CFR46.116(a)(1-8), 21CFR50.25(a)(1-8), FDA Information Sheets – Guide to Informed Consent, ICH Guidelines 4.8.5, IRB Guidebook III B			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB approved consent forms.			

Element ICS3B	The IRB identifies when the additional elements of information for informed consent forms are required as set forth in VA and other Federal regulations.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	Documentation exists in IRB minutes, or other forms of IRB documentation of IRB identification of whether any additional elements are required in 100% of sampled protocol files.	The IRB Chair and IRB members articulate the process of IRB consideration of when additional elements are required.	Consent forms contain one or more additional elements in 100% of sampled protocol files.	At least one sampled protocol file lacks evidence of IRB identification of whether any additional elements are required.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA will review a random sample of 16 files with written consent forms. If there are fewer than 16 such files in the sample, NCQA will review all files with written consent forms.			
Accreditation	0% ⇒ Accreditation is no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116(b)(1-6), M-3, Part I, Appendix 9C, 45CFR16.116(b)(1-6), 21CFR50.25(b)(1-6), FDA Information Sheets – Guide to Informed Consent, ICH Guidelines 4.8.5, IRB Guidebook III B			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB documentation, IRB approved consent forms.			

Element ICS3C	The IRB documents it's determination whether any additional element of informed consent is required.			
Weight (1-5)	1			
Scoring Guidelines	100%	75%	50%	0%
	IRB minutes or other IRB documentation provide evidence of IRB identification of whether any additional element of informed consent is required in 100% of sampled protocol files.	NA	NA	At least one sampled protocol file lacks documentation of IRB identification of whether additional elements of informed consent are required.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA will review a random sample of 16 files with written consent forms. If there are fewer than 16 such files in the sample, NCQA will review all files with written consent forms.			
Accreditation	0% ⇒ Accreditation no greater than Accredited			
Regulatory Support				
Data Sources	Materials			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB minutes, checklists, reviewer notes, IRB communications to investigators.			

Element ICS3D	IRB approved consent forms contain information concerning payment to subjects, including the amount and schedule of payments.			
Weight (1-5)	4			
Scoring Guidelines	100%	75%	50%	0%
	Information about element is present in 100% of sampled protocol files.	NA	NA	Information about element is present in less than 100% of sampled protocol files.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA will review a random sample of 16 files with written consent forms. If there are fewer than 16 such files in the sample, NCQA will review all files with written consent forms.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	M-3, Part I, 9.13, FDA Information Sheets – Payment to Research Subjects, ICH Guidelines 3.1.9			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB approved consent forms.			

Element ICS3E	No approved informed consent, whether oral or written, includes any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.			
Weight (1-5)	5			
Scoring Guidelines	100%	75%	50%	0%
	Consent forms do not contain statements waiving any of the subject's rights or releasing investigator or institution from liability in 100% of sampled protocol files.	NA	NA	At least one sampled protocol file contains a consent form with exculpatory language.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used. NCQA will review a random sample of 16 files with written consent forms. If there are fewer than 16 such files in the sample, NCQA will review all files with written consent forms.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116, M-3, Part I, Appendix 9C, 45CFR46.116, 21CFR50.20,FDA Information Sheets – Guide to Informed Consent, ICH Guidelines 4.8.5, IRB Guidebook III B			
Data Sources	Files			
Notes	Examples of documents that may demonstrate compliance with this element include: IRB documentation, IRB approved consent forms.			

Requirement ICS4	The IRB has policies and procedures regarding documentation of informed consent.			
Element ICS4A	The IRB requires informed consent to be documented by the use of a written consent form, VA Form 10-1086, approved by the IRB and signed by the subject or the subject's legally authorized representative, except in cases where the documentation of informed consent is waived by the IRB.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	M-3, Part I, 9.09a(4), M-3, Part I, 9.11(b)			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			
Element ICS4B	IRB policies describe situations where the signature of a witness is required.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.117(b)(2), M-3, Part I, 9.11b(2)(b), 45CFR46.117(b)(2), 21CFR50.27(b)(2)			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			

Element ICS4C	IRB policies describe the conditions, if any, under which a "short form" informed consent may be used. These conditions include the following: 1. There must be an oral presentation (in a language understandable to the subject) of all information contained in the completed informed consent document. 2. A short form written document (in the language understandable to the subject) to be presented to the subject includes a statement that the elements of informed consent have been presented orally. 3. A summary of the oral presentation is provided. (The English version of the informed consent document can serve as the summary). 4. The short form written document (in the language understandable to the subject) contains signature lines for both the subject and the witness to the consent process.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	Policies and procedures address all four factors.	NA	NA	Policies and procedures address less than four factors.	"Short form" is not used.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.117(b)(2), M-3, Part I, 9.11b(2)(b), 45CFR46.117(b)(2), 21CFR50.27(b)(2), IRB Guidebook III B				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.				

Element ICS4D	The IRB defines the conditions under which it will permit waiver of alteration of any element of informed consent or waive the requirement to obtain consent, if applicable, in accordance with VA and Federal regulations.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	38CFR16.116(c)(1-2), 38CFR(d)(1-4), M-3, Part I, Appendix 9C, 45CFR46.116(c)(1-2), 45CFR46.116(d)(1-4), 21CFR50.23, 21CFR50.24, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			

Element ICS4E	The IRB defines the conditions, if any, under which it allows for the waiver of documentation of informed consent in accordance with VA and Federal regulations, if applicable.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.	IRB does not grant waiver of documentation of consent.
Scope of Review	NCQA evaluates this element for each IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	38CFR16.117(c)(1-2), M-3, Part I, 9.11b(3), 45CFR46.117(c)(1-2), 21CFR50.23, 21CFR50.24, IRB Guidebook III B				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.				

ICSII	The IRB protects human subjects when exceptions from the informed consent requirements have been approved.

Requirement ICS5	The IRB has policies and procedures that allow for exceptions from the general requirements for obtaining informed consent before the use of a test article and appropriately reviews such exceptions.			
Element ICS5A	The IRB requires for each individual situation in which a test article is to be administered and informed consent may not feasibly be obtained, that the investigator and a physician who is not otherwise participating in the clinical investigation to certify in writing all of the following: 1. The subject is confronted by a life-threatening situation necessitating the use of the test article. 2. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from the subject. 3. Time is not sufficient to obtain consent from the subject's legal representative. 4. There is no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address all four factors.	NA	NA	Policies and procedures address less than four factors.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	21CFR50.23(a)(1), 21CFR50.23(a)(2), 21CFR50.23(a)(3), 21CFR50.23(a)(4), FDA Information Sheets – Emergency Use of Unapproved Medical Devices, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			
Element ICS5B	The IRB requires that if the immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination by a physician not otherwise participating in the study, in advance, the use of the test article shall be reviewed and evaluated within 5 working days in writing by a physician not participating in the investigation.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	21CFR50.23(b), FDA Information Sheets – Emergency Use of Unapproved Medical Devices, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			

Element ICS5C	The IRB requires documentation of emergency situations where exceptions to the general requirements for informed consent have occurred to be submitted to the IRB within five working days.			
Weight (1-5)	2			
Scoring Guidelines	100%	75%	50%	0%
	Policies and procedures address the element.	NA	NA	Policies and procedures do not address the element.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.			
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions			
Regulatory Support	21CFR50.23(c), FDA Information Sheets – Emergency Use of Unapproved Medical Devices, IRB Guidebook III B			
Data Sources	Documented process			
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.			

Requirement ICS6	The IRB has policies and procedures for exceptions from informed consent requirements in planned emergency research and systematically reviews such exceptions.				
Element ICS6A	The IRB requires that planned emergency research proposals include documentation of the following: 1. The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions. 2. Obtaining informed consent is not feasible. 3. Participation in research holds out the prospect of direct benefit to subjects. 4. The clinical investigation could not practically be carried out without the waiver. 5. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence and the investigator has committed to attempting to contact a legally authorized representative within that window of time. 6. The IRB has reviewed and approved informed consent procedures and an informed consent document as set forth in VA and other Federal regulations to be used in situations where the use of such procedures and documents is feasible. 7. Procedures are in place to inform, at the earliest feasible opportunity, each subject or legally authorized representative or family member, of the subject's inclusion in the clinical investigation. 8. There is a procedure to inform the subject, legally authorized representative or family member that the subject's participation may be discontinued at any time without penalty or loss of benefits to which the subject is otherwise entitled. 9. There must be a separate IND or IDE for the study for any FDA regulated product. 10. If the study does not involve an FDA-regulated product, there is concurrence by the Agency Secretary that the waiver is appropriate.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	Policies and procedures address all ten factors.	NA	NA	Policies and procedures address less than ten factors.	The institution does not conduct any planned emergency research.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	21CFR50.24(a)(1-6), 21CFR50.24(d), FDA Information Sheets – Informed Consent Exception, FDA Information Sheets – Planned Emergency Research, OPRR Reports 97-01				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.				

Element ICS6B	The IRB also requires, in planned emergency research proposals, that additional protections of the rights and welfare of the subjects will be provided through, at least the following: 1. Consultation with representatives of the community. 2. Public disclosure to the community prior to the study. 3. Public disclosure of the results of the investigation following completion. 4. Establishment of an independent data monitoring committee. 5. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.				
Weight (1-5)	2				
Scoring Guidelines	100%	75%	50%	0%	NA
	Policies and procedures address all five factors.	NA	NA	Policies and procedures address less than five factors.	The institution does not conduct any planned emergency research.
Scope of Review	NCQA evaluates this element for <u>each</u> IRB used.				
Accreditation	0% ⇒ Accreditation no greater than Accredited with Conditions				
Regulatory Support	21CFR50.24(a)(7)(i), 21CFR50.24(a)(7)(ii), 21CFR50.24(a)(7)(iii), 21CFR50.24(a)(7)(iv), 21CFR50.24(a)(7)(v), FDA Information Sheets – Informed Consent Exception, FDA Information Sheets – Planned Emergency Research				
Data Sources	Documented process				
Notes	Examples of documents that may demonstrate compliance with this element include: policies and procedures, investigator guidelines/instructions.				